

Orphan Products Designations and Approvals List
December 31, 2001

0695 00 JUN -5 14:45

Generic Name: **T-cell depleted stem cell enriched cellular product from peripheral blood stem cells**
Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of chronic granulomatous disease*
Sponsor: Nexell Therapeutics Inc.
Address: 9 Parker
Irvine CA 92618-1605
Date Designated: 11/1/2001
Market Approval Date: Not currently Approved

Generic Name: **(R)-N-[2-(6-chloro-5-methoxy-1H-indol-3-yl)propyl]acetamide**
Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of circadian rhythm sleep disorders in blind people with no light perception*
Sponsor: Phase 2 Discovery, Inc.
Address: 3130 Highland Avenue, Third Floor
Cincinnati OH 45219-2374
Date Designated: 10/3/2001
Market Approval Date: Not currently Approved

Generic Name: **1,5-(Butylimino)-1,5 dideoxy,D-glucitol**
Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of Fabry's disease.*
Sponsor: Oxford GlycoSciences
Address: 10, The Quadrant
Abington Science Park, Abington
Oxfordshire OX14 3YS UK
Date Designated: 5/12/1998
Market Approval Date: Not currently Approved

Generic Name: **1,5-(Butylimino)-1,5 dideoxy,D-glucitol**
Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of Gaucher disease.*
Sponsor: Oxford GlycoSciences
Address: 10, The Quadrant
Abington Science Park, Abington
Oxfordshire OX14 3YS UK
Date Designated: 5/29/1998
Market Approval Date: Not currently Approved

84N-0102

LS T 99

Generic Name: **1-(11-dodecylamino-10-hydroxyundecyl)-3,7-dimethylxanthine hydrogen methanesulfonate** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of hormone refractory prostate carcinoma.*
Sponsor: Cell Therapeutics, Inc. Date Designated: 1/18/2000
Address: 201 Elliott Avenue West Market Approval Date: Not currently Approved
Suite 400
Seattle WA 98119

Generic Name: **111Indium pentetreotide** Trade Name: **SomatoTher**
Designated Indication: *Treatment of somatostatin receptor positive neuroendocrine tumors.*
Sponsor: Louisiana State University Medical Center Date Designated: 6/10/1999
Address: 1600 Canal St. Market Approval Date: Not currently Approved
10th Floor
New Orleans LA 70112

Generic Name: **15AU81** Trade Name: **Remodulin**
Designated Indication: *Treatment of pulmonary arterial hypertension.*
Sponsor: United Therapeutics Corp. Date Designated: 6/4/1997
Address: 68 T.W. Alexander Dr. Market Approval Date: Not currently Approved
P.O. Box 14186
Research Triangle Park NC 27709

Generic Name: **166Ho-DOTMP** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of multiple myeloma.*
Sponsor: NeoRx Corporation Date Designated: 2/10/1999
Address: 410 W. Harrison Street Market Approval Date: Not currently Approved
Seattle WA 98119-4007

Generic Name: **2'-deoxycytidine** Trade Name: **NONE ASSIGNED**
Designated Indication: *As a host-protective agent in the treatment of acute myelogenous leukemia.*
Sponsor: Grant, Steven M.D. Date Designated: 9/9/1996
Address: Massey Cancer Center, VCU Market Approval Date: Not currently Approved
P.O. Box 980230
Richmond VA 23298-0230

Generic Name: **2-0-desulfated heparin**

Trade Name: **Aeropin**

Designated Indication: *Treatment of cystic fibrosis.*

Sponsor: **Kennedy & Hoidal, M.D.'s**
Address: **University of Utah Health Sciences Center
50 North Medical Drive, Room 4R240
Salt Lake City UT 84132**

Date Designated: **9/17/1993**
Market Approval Date: **Not currently Approved**

Generic Name: **2-chloroethyl-3-sarcosinamide-1-nitrosourea**

Trade Name: **Sarmustine**

Designated Indication: *Treatment for malignant glioma*

Sponsor: **Pangene Corporation**
Address: **5500 Stewart Avenue
Fremont CA 94538**

Date Designated: **11/15/2001**
Market Approval Date: **Not currently Approved**

Generic Name: **2-chloroethyl-3-sarcosinamide-1-nitrosourea**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment for malignant gliomas*

Sponsor: **Lawrence Panasci, MD**
Address: **Professor of Medicine, McGill University
3755 Cote Ste Catherine
Montreal, Quebec H3T 1E2**

Date Designated: **8/3/2001**
Market Approval Date: **Not currently Approved**

Generic Name: **2-methoxyestradiol**

Trade Name: **Panzem**

Designated Indication: *Treatment of multiple myeloma*

Sponsor: **EntreMed, Inc.**
Address: **9640 Medical Center Drive
Rockville MD 20850**

Date Designated: **7/10/2001**
Market Approval Date: **Not currently Approved**

Generic Name: **24,25 dihydroxycholecalciferol**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of uremic osteodystrophy.*

Sponsor: **Lemmon Company**
Address: **1510 Delp Drive
Kulpsville PA 19443**

Date Designated: **2/27/1987**
Market Approval Date: **Not currently Approved**

Generic Name: **3,4-diaminopyridine**

Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of Lambert-Eaton myasthenic syndrome.*

Sponsor: Jacobus Pharmaceutical Company
Address: 37 Cleveland Avenue
P.O. Box 5290
Princeton NJ 08540

Date Designated: 12/18/1990
Market Approval Date: Not currently Approved

Generic Name: **3,5,3'-triiodothyroacetate**

Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of well-differentiated papillary, follicular or combined papillary/follicular carcinomas of the thyroid gland.*

Sponsor: Elliot Danforth, Jr., M.D.
Address: University of Vermont
84 Beartown Road
Underhill VT 05489

Date Designated: 9/20/2000
Market Approval Date: Not currently Approved

Generic Name: **3-(3,5-Dimethyl-1H-2ylmethylene)-1,3-dihydro-indol-2-on**
e

Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of von Hippel-Lindau disease.*

Sponsor: Sugem, Inc.
Address: 230 East Grand Ave.
South San Francisco CA 94080

Date Designated: 3/23/2000
Market Approval Date: Not currently Approved

Generic Name: **3-(3,5-dimethyl-1H-2ylmethylene)-1,3-dihydro-indol-2-on**
e

Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of Kaposi's sarcoma.*

Sponsor: Sugem, Inc.
Address: 230 East Grand Ave.
South San Francisco CA 94080-4811

Date Designated: 9/11/1998
Market Approval Date: Not currently Approved

Generic Name: **3-(4'aminoisoindoline-1'-one)-1-piperidine-2,6-dione**

Trade Name: Revimid (proposed)

Designated Indication: *Treatment for multiple myeloma*

Sponsor: Cellegene Corporation
Address: 7 Powder Horn Drive
Warren NJ 07059

Date Designated: 9/20/2001
Market Approval Date: Not currently Approved

Generic Name: **4-aminosalicylic acid** Trade Name: **Pamisyl (P-D), Rezipas (Squibb)**
Designated Indication: *Treatment of mild to moderate ulcerative colitis in patients intolerant to sulfasalazine.*
Sponsor: **Beeken, Warren M.D.** Date Designated: **12/13/1989**
Address: **University Of Vermont** Market Approval Date: **Not currently Approved**
Given C-317
Burlington VT 05405

Generic Name: **40SD02** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of chronic iron overload resulting from conventional transfusional treatment of beta-thalassemia major and sickle cell anemia.*
Sponsor: **Biomedical Frontiers, Inc.** Date Designated: **12/21/1998**
Address: **1095 10th Ave., S.E.** Market Approval Date: **Not currently Approved**
Minneapolis MN 55414

Generic Name: **5,6-dihydro-5-azacytidine** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of malignant mesothelioma.*
Sponsor: **ILEX Oncology, Inc.** Date Designated: **5/11/1992**
Address: **4545 Horizon Hill Blvd.** Market Approval Date: **Not currently Approved**
San Antonio TX 78229-2263

Generic Name: **5-aza-2'-deoxycytidine** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of acute leukemia.*
Sponsor: **SuperGen, Inc.** Date Designated: **8/3/1987**
Address: **4140 Dublin Blvd.** Market Approval Date: **Not currently Approved**
Suite 200
Dublin CA 94568

Generic Name: **506U78** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of chronic lymphocytic leukemia.*
Sponsor: **Glaxo Wellcome, Inc.** Date Designated: **9/2/1999**
Address: **Five Moore Dr.** Market Approval Date: **Not currently Approved**
P.O. Box 13398
Research Triangle Park NC 27709-3398

Generic Name: **6-hydroxymethylacylfulvene**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of histologically confirmed advanced or metastatic pancreatic cancer.*

Sponsor: **MGI Pharma, Inc.**
Address: **6300 West Old Shakoppe Rd.
Suite 110
Bloomington MN 55438-2318**

Date Designated: **4/6/1999**
Market Approval Date: **Not currently Approved**

Generic Name: **6-hydroxymethylacylfulvene**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of ovarian cancer.*

Sponsor: **MGI Pharma, Inc.**
Address: **5775 West Old Shakoppe Rd.
Suite 100
Bloomington MN 55437-3107**

Date Designated: **7/6/1999**
Market Approval Date: **Not currently Approved**

Generic Name: **6-hydroxymethylacylfulvene**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of renal cell carcinoma.*

Sponsor: **MGI Pharma, Inc.**
Address: **6300 West Old Shakoppe Rd.
Suite 110
Bloomington MN 55438-2318**

Date Designated: **7/27/1999**
Market Approval Date: **Not currently Approved**

Generic Name: **8 Cyclopentyl 1,3-dipropylxanthine**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of cystic fibrosis.*

Sponsor: **SciClone Pharmaceuticals, Inc.**
Address: **901 Mariner's Island Boulevard
San Mateo CA 94404-1593**

Date Designated: **3/24/1997**
Market Approval Date: **Not currently Approved**

Generic Name: **8-methoxsalen**

Trade Name: **Uvadex**

Designated Indication: *For the prevention of acute rejection of cardiac allografts.*

Sponsor: **Therakos, Inc.**
Address: **Oaklands Corporate Center
437 Creamery Way
Exton PA 19341**

Date Designated: **5/12/1994**
Market Approval Date: **Not currently Approved**

Generic Name: **8-methoxsalen**

Trade Name: **Uvadex**

Designated Indication: *For use in conjunction with the UVAR photopheresis to treat diffuse systemic sclerosis.*

Sponsor: **Therakos, Inc.**
Address: **Oaklands Corporate Center
437 Creamery Way
Exton PA 19341**

Date Designated: **6/22/1993**
Market Approval Date: **Not currently Approved**

Generic Name: **9-cis retinoic acid**

Trade Name: **Panretin**

Designated Indication: *Treatment of acute promyelocytic leukemia.*

Sponsor: **Ligand Pharmaceuticals, Inc.**
Address: **9393 Towne Centre Drive
Suite 100
San Diego CA 92121**

Date Designated: **4/10/1992**
Market Approval Date: **Not currently Approved**

Generic Name: **9-nitro-20-(S)-camptothecin**

Trade Name: **Camvirex**

Designated Indication: *Treatment of pediatric HIV infection/AIDS*

Sponsor: **NovoMed Pharmaceuticals, Inc.**
Address: **P.O. Box 900
Germantown MD 20875-0900**

Date Designated: **5/15/2001**
Market Approval Date: **Not currently Approved**

Generic Name: **9-nitro-20-(S)-camptothecin**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of pancreatic cancer.*

Sponsor: **Stehlin Foundation for Cancer Research**
Address: **1315 St. Joseph Parkway, Suite 1818
Houston TX 77002**

Date Designated: **9/16/1996**
Market Approval Date: **Not currently Approved**

Generic Name: **Abetimus**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of lupus nephritis.*

Sponsor: **La Jolla Pharmaceutical Co.**
Address: **6455 Nancy Ridge Dr.
San Diego CA 92121**

Date Designated: **7/28/2000**
Market Approval Date: **Not currently Approved**

Generic Name: **acetylcysteine**

Trade Name: **Acetadote**

Designated Indication: *For the intravenous treatment of moderate to severe acetaminophen overdose*

Sponsor: **Cumberland Pharmaceuticals Inc.**
Address: **209 10th Street South
Suite 332
Nashville TN 37203**

Date Designated: **10/19/2001**
Market Approval Date: **Not currently Approved**

Generic Name: **Acetylcysteine**

Trade Name: **Mucomyst/Mucomyst 10 IV**

Designated Indication: *Intravenous treatment of patients presenting with moderate to severe acetaminophen overdose.*

Sponsor: **Bristol-Myers Squibb Company**
Address: **P.O. Box 4500
Princeton NJ 08543-4500**

Date Designated: **8/13/1987**
Market Approval Date: **Not currently Approved**

Generic Name: **Aconiazide**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of tuberculosis.*

Sponsor: **Lincoln Diagnostics**
Address: **P.O. Box 1128
Decatur IL 62525**

Date Designated: **6/20/1988**
Market Approval Date: **Not currently Approved**

Generic Name: **Adeno-associated viral vector containing the gene for human coagulation factor IX**

Trade Name: **Coagulin-B**

Designated Indication: *Intramuscular treatment of patients with moderate to severe hemophilia*

Sponsor: **Avigen, Inc.**
Address: **1301 Harbor Bay Parkway
Alameda CA 94502**

Date Designated: **6/13/2001**
Market Approval Date: **Not currently Approved**

Generic Name: **Adeno-associated viral vector containing the gene for human coagulation factor IX**

Trade Name: **Coagulin-B**

Designated Indication: *Intrahepatic treatment of patients with moderate to severe hemophilia*

Sponsor: **Avigen, Inc.**
Address: **1301 Harbor Bay Parkway
Alameda CA 94502**

Date Designated: **6/13/2001**
Market Approval Date: **Not currently Approved**

Generic Name: **Adeno-associated viral-based vector cystic fibrosis gene therapy** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of cystic fibrosis.*
Sponsor: **Targeted Genetics Corporation** Date Designated: **2/15/1995**
Address: **1100 Olive Way, Suite 100** Market Approval Date: **Not currently Approved**
Seattle WA 98101

Generic Name: **Adenovirus-based vector Factor VIII complementary DNA to somatic cells** Trade Name: **MiniAdFVIII**
Designated Indication: *Treatment of hemophilia A.*
Sponsor: **GenStar Therapeutics Corporation** Date Designated: **12/15/1999**
Address: **10835 Altman Row** Market Approval Date: **Not currently Approved**
Suite 150
San Diego CA 92121

Generic Name: **adenovirus-mediated herpes simplex virus-thymidine kinase gene** Trade Name: **NONE ASSIGNED**
Designated Indication: *Use with gancyclovir in the treatment of malignant glioma*
Sponsor: **Ark Therapeutics Ltd** Date Designated: **7/31/2001**
Address: **6 Warren Mews** Market Approval Date: **Not currently Approved**
London W1T6AR UK

Generic Name: **Albendazole** Trade Name: **Albenza**
Designated Indication: *Treatment of hydatid disease (cystic echinococcosis due to E. granulosus larvae or alveolar echinococcosis due to E. multilocularis larvae).*
Sponsor: **SmithKline Beecham Pharmaceuticals** Date Designated: **1/17/1996**
Address: **One Franklin Plaza** Market Approval Date: **6/11/1996**
P.O. Box 7929
Philadelphia PA 19101

Generic Name: **Albendazole** Trade Name: **Albenza**
Designated Indication: *Treatment of neurocysticercosis due to Taenia solium as: 1) chemotherapy of parenchymal, subarachnoidal and racemose (cysts in spinal fluid) neurocysticercosis in symptomatic cases and 2) prophylaxis of epilepsy and other sequelae in asymptomatic neurocysticercosis.*
Sponsor: **SmithKline Beecham Pharmaceuticals** Date Designated: **1/18/1996**
Address: **One Franklin Plaza** Market Approval Date: **6/11/1996**
P.O. Box 7929
Philadelphia PA 19101

Generic Name: **Aldesleukin** Trade Name: **Proleukin**
Designated Indication: *For the treatment non-Hodgkin's lymphoma.*
Sponsor: Chiron Corporation Date Designated: 11/24/1998
Address: 4560 Horton St. Market Approval Date: Not currently Approved
Emeryville CA 94608-2916

Generic Name: **Aldesleukin** Trade Name: **Proleukin**
Designated Indication: *Treatment of metastatic melanoma.*
Sponsor: Chiron Corporation Date Designated: 9/10/1996
Address: 4560 Horton Street Market Approval Date: 1/9/1998
Emeryville CA 94608-2916

Generic Name: **Aldesleukin** Trade Name: **Proleukin**
Designated Indication: *Treatment of primary immunodeficiency disease associated with T-cell defects.*
Sponsor: Chiron Corporation Date Designated: 3/22/1989
Address: 4560 Horton Street Market Approval Date: Not currently Approved
Emeryville CA 94608-2916

Generic Name: **Aldesleukin** Trade Name: **Proleukin**
Designated Indication: *Treatment of metastatic renal cell carcinoma.*
Sponsor: Chiron Corporation Date Designated: 9/14/1988
Address: 4560 Horton Street Market Approval Date: 5/5/1992
Emeryville CA 94608-2916

Generic Name: **Aldesleukin** Trade Name: **Proleukin**
Designated Indication: *Treatment of acute myelogenous leukemia.*
Sponsor: Chiron Corporation Date Designated: 7/31/1998
Address: 4560 Horton St. Market Approval Date: Not currently Approved
Emeryville CA 94608-2916

Generic Name: **alemtuzumab** Trade Name: **Campath**
Designated Indication: *Treatment of chronic lymphocytic leukemia.*
Sponsor: **Millennium and ILEX Partners, LP** Date Designated: **10/20/1997**
Address: **75 Sidney Street** Market Approval Date: **5/7/2001**
Cambridge MA 02138

Generic Name: **Alendronate disodium** Trade Name: **Fosamax**
Designated Indication: *Treatment of the bone manifestations of Gaucher disease*
Sponsor: **Richard J. Wenstrup, M.D.** Date Designated: **2/13/2001**
Address: **Division of Human Genetics** Market Approval Date: **Not currently Approved**
Children's Hospital Research Foundation
Cincinnati OH 45229-3039

Generic Name: **Alglucerase injection** Trade Name: **Ceredase**
Designated Indication: *For replacement therapy in patients with Gaucher's disease type I.*
Sponsor: **Genzyme Corporation** Date Designated: **3/11/1985**
Address: **One Kendall Square** Market Approval Date: **4/5/1991**
Cambridge MA 02139-1562

Generic Name: **Alglucerase injection** Trade Name: **Ceredase**
Designated Indication: *Replacement therapy in patients with Type II and III Gaucher's disease.*
Sponsor: **Genzyme Corporation** Date Designated: **7/21/1995**
Address: **One Kendall Square** Market Approval Date: **Not currently Approved**
Cambridge MA 02139-1562

Generic Name: **Alitretinoin** Trade Name: **Panretin**
Designated Indication: *Topical treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma.*
Sponsor: **Ligand Pharmaceuticals Inc.** Date Designated: **3/24/1998**
Address: **10275 Science Center Drive** Market Approval Date: **2/2/1999**
San Diego CA 92121-1117

Generic Name: **Allogeneic human retinal pigment epithelial cells on gelatin microcarriers** Trade Name: **Spheramine**
Designated Indication: *Treatment of Hoehn and Yahr stage 3 and 4 Parkinson's disease.*
Sponsor: **Titan Pharmaceuticals, Inc.** Date Designated: **7/18/1997**
Address: **Post Office Plaza** Market Approval Date: **Not currently Approved**
50 Division Street, Suite 503
Somerville NJ 08876

Generic Name: **Allogeneic peripheral blood mononuclear cells sensitized against patient alloantigens by mixed lymphocyte culture** Trade Name: **CYTOIMPLANT**
Designated Indication: *Treatment of pancreatic cancer.*
Sponsor: **Applied Immunotherapeutics, LLC** Date Designated: **6/13/1997**
Address: **14132 E. Firestone Boulevard** Market Approval Date: **Not currently Approved**
Santa Fe Springs CA 90670

Generic Name: **Allopurinol sodium** Trade Name: **Zyloprim for Injection**
Designated Indication: *Management of patients with leukemia, lymphoma, and solid tumor malignancies who are receiving cancer therapy which causes elevations of serum and urinary uric acid levels and who cannot tolerate oral therapy.*
Sponsor: **Catalytica Pharmaceuticals, Inc** Date Designated: **10/16/1992**
Address: **PO Box 1887** Market Approval Date: **5/17/1996**
Greenville NC 27835-1887

Generic Name: **Alpha-galactosidase A** Trade Name: **CC-galactosidase**
Designated Indication: *Treatment of alpha-galactosidase A deficiency (Fabry's disease).*
Sponsor: **Orphan Medical, Inc.** Date Designated: **6/17/1991**
Address: **13911 Ridgedale Drive** Market Approval Date: **Not currently Approved**
Suite 475
Minnetonka MN 55305

Generic Name: **Alpha-galactosidase A** Trade Name: **Fabrase**
Designated Indication: *Treatment of Fabry's disease.*
Sponsor: **Desnick, Robert J. M.D.** Date Designated: **7/20/1990**
Address: **The Mount Sinai School Of Medicine** Market Approval Date: **Not currently Approved**
Fifth Avenue at 100th Street, Box 1203
New York NY 10029

Generic Name: **Alpha-galactosidase A** Trade Name: **Replagal**
Designated Indication: *Long-term enzyme replacement therapy for the treatment of Fabry disease.*
Sponsor: **Transkaryotic Therapies Inc.** Date Designated: **6/22/1998**
Address: **195 Albany St.** Market Approval Date: **Not currently Approved**
Cambridge MA 02139

Generic Name: **Alpha-melanocyte stimulating hormone** Trade Name: **NONE ASSIGNED**
Designated Indication: *Prevention and treatment of intrinsic acute renal failure due to ischemia.*
Sponsor: **National Institute of Diabetes, and Digestive** Date Designated: **8/19/1997**
Address: **National Institutes of Health, 31 Center Drive** Market Approval Date: **Not currently Approved**
Building 31, Room 9N-222
Bethesda MD 20892-2560

Generic Name: **Alpha1-proteinase inhibitor (human)** Trade Name: **Prolastin**
Designated Indication: *For replacement therapy in the alpha-1-proteinase inhibitor congenital deficiency state.*
Sponsor: **Bayer Corporation** Date Designated: **12/7/1984**
Address: **Pharmaceutical Division, Biological Products** Market Approval Date: **12/2/1987**
400 Morgan Lane
New Haven CT 06516

Generic Name: **Alpha1-proteinase inhibitor (human)** Trade Name: **NONE ASSIGNED**
Designated Indication: *For slowing the progression of emphysema in alpha1-antitrypsin deficient patients.*
Sponsor: **Aventis Behring L.L.C.** Date Designated: **11/24/1999**
Address: **1020 First Ave.** Market Approval Date: **Not currently Approved**
PO Box 61501
King of Prussia PA 19406-0901

Generic Name: **Alronidase** Trade Name: **Aldurazyme**
Designated Indication: *Treatment of patients with mucopolysaccharidosis-I.*
Sponsor: **BioMarin Pharmaceutical, Inc.** Date Designated: **9/24/1997**
Address: **371 Bel Marin Keys Boulevard, Suite 210** Market Approval Date: **Not currently Approved**
Novato CA 94949-5608

Generic Name: **Altretamine** Trade Name: **Hexalen**
Designated Indication: *Treatment of advanced adenocarcinoma of the ovary.*
Sponsor: Medimmune Oncology, Inc. Date Designated: 2/9/1984
Address: One Tower Bridge Market Approval Date: 12/26/1990
100 Front Street, Suite 400
West Conshohocken PA 19428

Generic Name: **Amifostine** Trade Name: **Ethyol**
Designated Indication: *For use as a chemoprotective agent for cyclophosphamide in the treatment of advanced ovarian carcinoma.*
Sponsor: Medimmune Oncology, Inc. Date Designated: 5/30/1990
Address: 35 West Watkins Mill Rd. Market Approval Date: Not currently Approved
Gaithersburg MD 20878

Generic Name: **Amifostine** Trade Name: **Ethyol**
Designated Indication: *For the reduction of the incidence and severity of toxicities associated with cisplatin administration.*
Sponsor: Medimmune Oncology, Inc. Date Designated: 11/24/1998
Address: 35 West Watkins Mill Rd. Market Approval Date: Not currently Approved
Gaithersburg MD 20878

Generic Name: **Amifostine** Trade Name: **Ethyol**
Designated Indication: *Treatment of myelodysplastic syndromes.*
Sponsor: Medimmune Oncology, Inc. Date Designated: 10/4/1999
Address: 35 West Watkins Mill Rd. Market Approval Date: Not currently Approved
Gaithersburg MD 20878

Generic Name: **Amifostine** Trade Name: **Ethyol**
Designated Indication: *For use as a chemoprotective agent for cisplatin in the treatment of metastatic melanoma.*
Sponsor: Medimmune Oncology, Inc. Date Designated: 5/30/1990
Address: 35 West Watkins Mills Rd. Market Approval Date: Not currently Approved
Gaithersburg MD 20878

Generic **Amifostine**
Name:

Trade **Ethiol**
Name:

Designated *For use as a chemoprotective agent for cisplatin in the treatment of advanced ovarian carcinoma.*
Indication:

Sponsor: Medimmune Oncology, Inc.
Address: One Tower Bridge
100 Front Street, Suite 400
West Conshohocken PA 19428

Date Designated: 5/30/1990
Market Approval Date: 12/8/1995

Generic **Amifostine**
Name:

Trade **Ethiol**
Name:

Designated *Reduction of the incidence of moderate to severe xerostomia in patients undergoing post-operative radiation*
Indication: *treatment for head and neck cancer.*

Sponsor: Medimmune Oncology, Inc.
Address: One Tower Bridge
100 Front Street, Suite 400
Conshohocken PA 19428

Date Designated: 5/12/1998
Market Approval Date: 6/24/1999

Generic **Aminocaproic acid**
Name:

Trade **Caprogel**
Name:

Designated *For the topical treatment of traumatic hyphema of the eye.*
Indication:

Sponsor: Eastern Virginia Medical School
Address: Department of Ophthalmology
880 Kempsville Road, Suite 2500
Norfolk VA 23502-3990

Date Designated: 1/6/1995
Market Approval Date: Not currently Approved

Generic **Aminosalicilic acid**
Name:

Trade **Paser Granules**
Name:

Designated *Treatment of tuberculosis infections.*
Indication:

Sponsor: Jacobus Pharmaceutical Company
Address: 37 Cleveland Lane
P.O. Box 5290
Princeton NJ 08540

Date Designated: 2/19/1992
Market Approval Date: 6/30/1994

Generic **Aminosidine**
Name:

Trade **Paromomycin**
Name:

Designated *Treatment of visceral leishmaniasis (kala-azar).*
Indication:

Sponsor: Kanyok, Thomas P. Pharm.D.
Address: University of Illinois at Chicago College of
833 South Wood Street (m/c886) Rm. 176
Chicago IL 60612

Date Designated: 9/9/1994
Market Approval Date: Not currently Approved

Generic Name: **Aminosidine** Trade Name: **Gabbromicina**
Designated Indication: *Treatment of Mycobacterium avium complex.*
Sponsor: Kanyok, Thomas P. Pharm.D. Date Designated: 11/15/1993
Address: University of Illinois at Chicago College of Market Approval Date: Not currently Approved
833 South Wood Street (m/c886) Rm. 176
Chicago IL 60612

Generic Name: **Aminosidine** Trade Name: **Gabbromicina**
Designated Indication: *Treatment of tuberculosis.*
Sponsor: Kanyok, Thomas P. Pharm.D. Date Designated: 5/14/1993
Address: University Of Illinois At Chicago College of Market Approval Date: Not currently Approved
833 South Wood Street (m/c886) Rm. 176
Chicago IL 60612

Generic Name: **Amiodarone** Trade Name: **Amio-Aqueous**
Designated Indication: *Treatment of incessant ventricular tachycardia.*
Sponsor: Wyeth-Ayerst Research Date Designated: 8/17/1993
Address: PO Box 8299 Market Approval Date: Not currently Approved
Philadelphia PA 19101-8299

Generic Name: **Amiodarone HCl** Trade Name: **Cordarone**
Designated Indication: *For the acute treatment and prophylaxis of life-threatening ventricular tachycardia or ventricular fibrillation.*
Sponsor: Wyeth-Ayerst Laboratories Date Designated: 3/16/1994
Address: P.O. Box 8299 Market Approval Date: 8/3/1995
Philadelphia PA 19101

Generic Name: **Ammonium tetrathiomolybdate** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of Wilson's disease.*
Sponsor: Brewer, George J. M.D. Date Designated: 1/31/1994
Address: University Of Michigan Medical School Market Approval Date: Not currently Approved
4708 Medical Science Building II 0618
Ann Arbor MI 48109

Generic Name: **Amphotericin B lipid complex**

Trade Name: **Abelcet**

Designated Indication: *Treatment of invasive fungal infections.*

Sponsor: **Liposome Company, Inc.**
Address: **One Research Way
Princeton NJ 08540**

Date Designated: **12/3/1996**
Market Approval Date: **10/18/1996**

Generic Name: **Anagrelide**

Trade Name: **Agrylin**

Designated Indication: *Treatment of polycythemia vera.*

Sponsor: **Roberts Pharmaceutical Corp.**
Address: **Meridian Center II
4 Industrial Way West
Eatontown NJ 07724-2274**

Date Designated: **6/11/1985**
Market Approval Date: **Not currently Approved**

Generic Name: **Anagrelide**

Trade Name: **Agrylin**

Designated Indication: *Treatment of essential thrombocythemia.*

Sponsor: **Roberts Pharmaceutical Corp.**
Address: **Meridian Center III
6 Industrial Way West
Eatontown NJ 07724**

Date Designated: **1/27/1988**
Market Approval Date: **3/14/1997**

Generic Name: **Anagrelide**

Trade Name: **Agrylin**

Designated Indication: *Treatment of thrombocytosis in chronic myelogenous leukemia.*

Sponsor: **Roberts Pharmaceutical Corp.**
Address: **Meridian Center II
4 Industrial Way West
Eatontown NJ 07724-2274**

Date Designated: **7/14/1986**
Market Approval Date: **Not currently Approved**

Generic Name: **Ananain, comosain**

Trade Name: **Vianain**

Designated Indication: *For the enzymatic debridement of severe burns.*

Sponsor: **Genzyme Corporation**
Address: **One Kendall Square
Cambridge MA 02139**

Date Designated: **1/21/1992**
Market Approval Date: **Not currently Approved**

Generic Name: **Ancestim** Trade Name: **Stemgen**
Designated Indication: *For use in combination with filgrastim to decrease the number of phereses required to collect peripheral blood progenitor cells capable of providing rapid multi-lineage hematopoietic reconstitution following myelosuppressive or myeloablative therapy.*
Sponsor: **Amgen, Inc.** Date Designated: **7/5/1995**
Address: **One Amgen Center Drive** Market Approval Date: **Not currently Approved**
Thousand Oaks CA 91320-1799

Generic Name: **Ancrod** Trade Name: **Viprinex**
Designated Indication: *To establish and maintain anticoagulation in heparin-intolerant patients undergoing cardiopulmonary bypass.*
Sponsor: **Knoll Pharmaceutical Company** Date Designated: **10/20/1989**
Address: **3000 Continental Dr., North** Market Approval Date: **Not currently Approved**
Mt. Olive NJ 07828

Generic Name: **Angiotensin 1-7** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of neutropenia associated with autologous bone marrow transplantation.*
Sponsor: **Maret Pharmaceuticals** Date Designated: **2/16/2000**
Address: **4041 MacArthur Blvd.** Market Approval Date: **Not currently Approved**
Suite 375
Newport Beach CA 92660

Generic Name: **Angiotensin 1-7** Trade Name: **MARstem**
Designated Indication: *Treatment of myelodysplastic syndrome*
Sponsor: **Maret Pharmaceutical Corporation** Date Designated: **8/3/2001**
Address: **4041 MacArthur Boulevard, Suite 375** Market Approval Date: **Not currently Approved**
Newport Beach CA 92660

Generic Name: **Anti-thymocyte Globulin (Rabbit)** Trade Name: **Thymoglobulin**
Designated Indication: *Treatment of myelodysplastic syndrome (MDS)*
Sponsor: **SangStat Medical Corporation** Date Designated: **9/6/2000**
Address: **6300 Dumbarton Circle** Market Approval Date: **Not currently Approved**
Freemont CA 94555

Generic Name: **Anti-thymocyte serum** Trade Name: **Nashville Rabbit Anti-thymocyte Serum**
Designated Indication: *Treatment of allograft rejection, including solid organ (kidney, liver, heart, lung, and pancreas) and bone marrow transplantation.*
Sponsor: **Applied Medical Research** Date Designated: **6/2/1993**
Address: **1600 Hayes Street** Market Approval Date: **Not currently Approved**
Nashville TN 37203

Generic Name: **Antiepilepsirine** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of drug resistant generalized tonic-clonic epilepsy in children and adults.*
Sponsor: **Children's Hospital** Date Designated: **3/23/1989**
Address: **700 Children's Drive** Market Approval Date: **Not currently Approved**
Columbus OH 43205

Generic Name: **Antihemophilic factor (human)** Trade Name: **Alphanate**
Designated Indication: *Treatment of von Willebrand's disease.*
Sponsor: **Alpha Therapeutic Corporation** Date Designated: **1/5/1996**
Address: **5555 Valley Boulevard** Market Approval Date: **Not currently Approved**
Los Angeles CA 90032-3520

Generic Name: **Antihemophilic factor (recombinant)** Trade Name: **Kogenate**
Designated Indication: *Prophylaxis and treatment of bleeding in individuals with hemophilia A or for prophylaxis when surgery is required in individuals with hemophilia A.*
Sponsor: **Bayer Corporation** Date Designated: **9/25/1989**
Address: **1884 Miles Avenue** Market Approval Date: **2/25/1993**
Elkhart IN 46515

Generic Name: **Antihemophilic factor (recombinant)** Trade Name: **ReFacto**
Designated Indication: *For the control and prevention of hemorrhagic episodes and for surgical prophylaxis in patients with hemophilia A (congenital factor VIII deficiency or classic hemophilia).*
Sponsor: **Genetics Institute, Inc.** Date Designated: **2/8/1996**
Address: **87 CambridgePark Drive** Market Approval Date: **Not currently Approved**
Cambridge MA 02140

Generic Name: **Antihemophilic factor/von Willebrand factor complex (human), dried, pasteurized** Trade Name: **Humate-P**
Designated Indication: *Treatment and prevention of bleeding in hemophilia A (classical hemophilia) in adult patients; and treatment of spontaneous and trauma-induced bleeding episodes in severe von Willebrand disease, and in mild and moderate von Willebrand disease where use of desmopressin is known or suspected to be inadequate in adult and pediatric*
Sponsor: **Aventis Behring L.L.C.** Date Designated: **10/16/1992**
Address: **1020 First Avenue** Market Approval Date: **4/1/1999**
PO Box 61501
King Of Prussia PA 19406-0901

Generic Name: **Antithrombin III (human)** Trade Name: **ATnativ**
Designated Indication: *For the treatment of patients with hereditary antithrombin III deficiency in connection with surgical or obstetrical procedures or when they suffer from thromboembolism.*
Sponsor: **Pharmacia & Upjohn AB** Date Designated: **2/8/1985**
Address: **Lindhagensgatan 133** Market Approval Date: **12/13/1989**
SE-112 87 Stockholm
Sweden SE

Generic Name: **Antithrombin III (human)** Trade Name: **Thrombate III**
Designated Indication: *For replacement therapy in congenital deficiency of AT-III for prevention and treatment of thrombosis and pulmonary emboli.*
Sponsor: **Bayer Corporation** Date Designated: **11/26/1984**
Address: **Pharmaceutical Division, Biological Products** Market Approval Date: **12/30/1991**
400 Morgan Lane
New Haven CT 06516

Generic Name: **Antithrombin III (human) concentrate IV** Trade Name: **Kybernin P**
Designated Indication: *For prophylaxis and treatment of thromboembolic episodes in patients with genetic AT-III deficiency.*
Sponsor: **Aventis Behring L.L.C.** Date Designated: **7/2/1985**
Address: **1020 First Ave.** Market Approval Date: **Not currently Approved**
PO Box 61501
King of Prussia PA 19406-0901

Generic Name: **Antithrombin III human** Trade Name: **Antithrombin III human**
Designated Indication: *Preventing or arresting episodes of thrombosis in patients with congenital AT-III deficiency and/or to prevent the occurrence of thrombosis in patients with AT-III deficiency who have undergone trauma or who are about to undergo surgery or parturition.*
Sponsor: **American National Red Cross** Date Designated: **1/2/1986**
Address: **9312 Old Georgetown Road** Market Approval Date: **Not currently Approved**
Bethesda MD 20814

Generic Name: **Antivenin, crotalidae polyvalent immune Fab (ovine)** Trade Name: **CroFab**
Designated Indication: *Treatment of envenomations inflicted by North American crotalid snakes.*
Sponsor: **Protherics, Inc.** Date Designated: **1/12/1994**
Address: **1207 17th Ave. S., Suite 103** Market Approval Date: **10/2/2000**
Nashville TN 37212

Generic Name: **Antivenom (crotalidae) purified (avian)** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of envenomation by poisonous snakes belonging to the Crotalidae family.*
Sponsor: **Ophidian Pharmaceuticals, Inc.** Date Designated: **2/12/1991**
Address: **5445 East Cheryl Parkway** Market Approval Date: **Not currently Approved**
Madison WI 53711

Generic Name: **AP1903** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of acute graft-versus-host disease in patients undergoing bone marrow transplantation.*
Sponsor: **Ariad Gene Therapeutics, Inc.** Date Designated: **11/24/1999**
Address: **26 Landsdowne St.** Market Approval Date: **Not currently Approved**
Cambridge MA 02139-4234

Generic Name: **APL 400-020 V-Beta DNA vaccine** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of cutaneous T cell lymphoma.*
Sponsor: **Wyeth-Lederle Vaccines and Pediatrics** Date Designated: **3/8/1995**
Address: **211 Bailey Rd.** Market Approval Date: **Not currently Approved**
West Henrietta NY 14586-9728

Generic Name: **Apomorphine** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of the on-off fluctuations associated with late-stage Parkinson's disease.*
Sponsor: **Pentech Pharmaceuticals, Inc.** Date Designated: **7/17/1995**
Address: **1110 Lake Cook Rd.** Market Approval Date: **Not currently Approved**
Suite 257
Buffalo Grove IL 60089

Generic Name: **Apomorphine HCl** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of the on-off fluctuations associated with late-stage Parkinson's disease.*
Sponsor: Mylan Pharmaceuticals, Inc. Date Designated: 4/22/1993
Address: 781 Chestnut Ridge Rd. Market Approval Date: Not currently Approved
PO Box 4310
Morgantown WV 26505-4310

Generic Name: **Aprotinin** Trade Name: **Trasylol**
Designated Indication: *For prophylactic use to reduce perioperative blood loss and the homologous blood transfusion requirement in patients undergoing cardiopulmonary bypass surgery in the course of repeat coronary artery bypass graft surgery, and in selected cases of primary coronary artery bypass graft surgery where the risk of bleeding is especially high (impaired hemostasis) or where transfusion is unavailable or unacceptable.*
Sponsor: Bayer Corporation Date Designated: 11/17/1993
Address: Pharmaceutical Division Market Approval Date: 12/29/1993
400 Morgan Lane
West Haven CT 06516

Generic Name: **Arcitumomab** Trade Name: **99m Tc-labeled CEA-Scan**
Designated Indication: *Diagnosis and localization of primary, residual, recurrent and metastatic medullary thyroid carcinoma.*
Sponsor: Immunomedics, Inc. Date Designated: 5/10/1996
Address: 300 American Road Market Approval Date: Not currently Approved
Morris Plains NJ 07950

Generic Name: **Arginine butyrate** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of beta-hemoglobinopathies and beta-thalassemia.*
Sponsor: Perrine, Susan P., M.D. Date Designated: 4/7/1992
Address: Boston University Market Approval Date: Not currently Approved
Cancer Research Center
Boston MA 02118

Generic Name: **arsenic** Trade Name: **Trisenox**
Designated Indication: *Treatment of acute myelocytic leukemia subtypes M0, M1, M2, M4, M5, M6 and M7*
Sponsor: Cell Therapeutics, Inc. Date Designated: 11/2/2001
Address: 201 Elliott Avenue West Market Approval Date: Not currently Approved
Suite 400
Seattle WA 98119

Generic Name: **arsenic trioxide** Trade Name: **Trisenox**
Designated Indication: *Treatment of chronic myeloid leukemia*
Sponsor: Cell Therapeutics, Inc. Date Designated: 10/18/2001
Address: 201 Elliott Avenue West Market Approval Date: Not currently Approved
Suite 400
Seattle WA 98119

Generic Name: **Arsenic trioxide** Trade Name: **Trisenox**
Designated Indication: *Treatment of acute promyelocytic leukemia.*
Sponsor: Cell Therapeutics, Inc. Date Designated: 3/3/1998
Address: 201 Elliott Ave. West Market Approval Date: 9/25/2000
Suite 400
Seattle WA 98119

Generic Name: **arsenic trioxide** Trade Name: **Trisenox**
Designated Indication: *Treatment of myelodysplastic syndrome.*
Sponsor: Cell Therapeutics, Inc. Date Designated: 7/17/2000
Address: 201 Elliott Avenue West Market Approval Date: 9/25/2000
Suite 400
Seattle WA 98119

Generic Name: **Arsenic trioxide** Trade Name: **Trisenox**
Designated Indication: *Treatment of multiple myeloma.*
Sponsor: Cell Therapeutics, Inc. Date Designated: 4/28/2000
Address: 201 Elliott Ave. West, Suite 400 Market Approval Date: Not currently Approved
Seattle WA 98119

Generic Name: **Artesunate** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of malaria.*
Sponsor: World Health Organisation Date Designated: 7/19/1999
Address: Special Programme for Research and Training Market Approval Date: Not currently Approved
Via Appia, Geneva 27
Switzerland CH

Generic Name: **Atovaquone**

Trade Name: **Mepron**

Designated Indication: *Primary prophylaxis of HIV-infected persons at high risk for developing Toxoplasma gondii encephalitis.*

Sponsor: **Glaxo Wellcome Inc.**
Address: **5 Moore Drive**
PO Box 13398
Research Triangle Park NC 27709

Date Designated: **3/16/1993**
Market Approval Date: **Not currently Approved**

Generic Name: **Atovaquone**

Trade Name: **Mepron**

Designated Indication: *Treatment and suppression of Toxoplasma gondii encephalitis.*

Sponsor: **Glaxo Wellcome Inc.**
Address: **5 Moore Drive**
PO Box 13398
Research Triangle Park NC 27709-3398

Date Designated: **3/16/1993**
Market Approval Date: **Not currently Approved**

Generic Name: **Atovaquone**

Trade Name: **Mepron**

Designated Indication: *Prevention of Pneumocystis carinii pneumonia (PCP) in high-risk, HIV-infected patients defined by a history of one or more episodes of PCP and/or a peripheral CD4+ (T4 helper/inducer) lymphocyte count less than or equal to*

Sponsor: **Glaxo Wellcome Research and Development**
Address: **5 Moore Drive**
PO Box 13398
Research Triangle Park NC 27709

Date Designated: **8/14/1991**
Market Approval Date: **1/5/1999**

Generic Name: **Atovaquone**

Trade Name: **Mepron**

Designated Indication: *Treatment of AIDS associated Pneumocystis Carinii Pneumonia.*

Sponsor: **Glaxo Wellcome Inc.**
Address: **5 Moore Drive**
Research Triangle Park NC 27709

Date Designated: **9/10/1990**
Market Approval Date: **11/25/1992**

Generic Name: **augmerosen**

Trade Name: **Genasense**

Designated Indication: *Treatment of multiple myeloma*

Sponsor: **Genta Incorporated**
Address: **Two Oak Way**
Berkeley Heights NJ 07922

Date Designated: **8/28/2001**
Market Approval Date: **Not currently Approved**

Generic Name: **augmerosen** Trade Name: **Genasense**
Designated Indication: *Treatment of acute myelocytic leukemia*
Sponsor: **Genta Incorporated** Date Designated: **8/28/2001**
Address: **Two Oak Way** Market Approval Date: **Not currently Approved**
Berkeley Heights NJ 07922

Generic Name: **augmerosen** Trade Name: **Genasense**
Designated Indication: *Treatment of chronic lymphocytic leukemia*
Sponsor: **Genta Incorporated** Date Designated: **8/28/2001**
Address: **Two Oak Way** Market Approval Date: **Not currently Approved**
Berkeley Heights NJ 07922

Generic Name: **Autologous DNP-conjugated tumor vaccine** Trade Name: **M-Vax**
Designated Indication: *For adjuvant therapy in melanoma patients with surgically resectable lymph node metastasis (Stage III and limited Stage IV disease).*
Sponsor: **Avax Technologies, Inc.** Date Designated: **2/23/1999**
Address: **9200 Indian Creek Parkway** Market Approval Date: **Not currently Approved**
Building 9, Suite 200
Overland Park KS 66210

Generic Name: **Autolymphocyte therapy** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of renal cell carcinoma.*
Sponsor: **Cytogen Corporation** Date Designated: **7/12/1994**
Address: **600 College Road East** Market Approval Date: **Not currently Approved**
CN 5308
Princeton NJ 08540-5308

Generic Name: **azacitidine** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of myelodysplastic syndromes*
Sponsor: **Pharmion Corporation** Date Designated: **12/3/2001**
Address: **4865 Riverbend Road** Market Approval Date: **Not currently Approved**
Boulder CO 80301

Generic Name: **Azathioprine** Trade Name: **Imuran**
Designated Indication: *Treatment of oral manifestations of graft-versus-host disease.*
Sponsor: Oral Solutions, Inc. Date Designated: 9/14/1999
Address: 787 Seventh Ave., 48th Floor Market Approval Date: Not currently Approved
New York NY 10019

Generic Name: **B Lymphocyte Stimulator** Trade Name: **BLyS**
Designated Indication: *Treatment of common variable immunodeficiency (CVID)*
Sponsor: Human Genome Sciences, Inc. Date Designated: 2/21/2001
Address: 9410 Key West Avenue Market Approval Date: Not currently Approved
Rockville MD 20850

Generic Name: **Bacitracin** Trade Name: **Altracin**
Designated Indication: *Treatment of antibiotic-associated pseudomembranous enterocolitis caused by toxins A and B elaborated by Clostridium difficile.*
Sponsor: A. L. Laboratories, Inc. Date Designated: 3/13/1984
Address: One Executive Drive Market Approval Date: Not currently Approved
P.O. Box 1399
Fort Lee NJ 07024

Generic Name: **Baclofen** Trade Name: **Lioresal Intrathecal**
Designated Indication: *Treatment of intractable spasticity caused by spinal cord injury, multiple sclerosis, and other spinal diseases (including spinal ischemia, spinal tumor, transverse myelitis, cervical spondylosis, and degenerative myelopathy).*
Sponsor: Medtronic, Inc. Date Designated: 11/10/1987
Address: 800 53rd Avenue N.E. Market Approval Date: 6/25/1992
Minneapolis MN 55432

Generic Name: **Baclofen** Trade Name: **Lioresal Intrathecal**
Designated Indication: *Treatment of spasticity associated with cerebral palsy.*
Sponsor: Medtronic, Inc. Date Designated: 9/26/1994
Address: 800 53rd Avenue N.E. Market Approval Date: Not currently Approved
P.O. 1250
Minneapolis MN 55440-9087

Generic Name: **Baclofen**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of intractable spasticity due to multiple sclerosis or spinal cord injury.*

Sponsor: **Infusaid, Inc.**
Address: **1400 Providence Highway
Norwood MA 02062**

Date Designated: **12/16/1991**
Market Approval Date: **Not currently Approved**

Generic Name: **Basiliximab**

Trade Name: **Simulect**

Designated Indication: *Prophylaxis of solid organ rejection.*

Sponsor: **Novartis Pharmaceuticals Corporation**
Address: **59 Route 10
East Hanover NJ 07936-1080**

Date Designated: **12/12/1997**
Market Approval Date: **5/12/1998**

Generic Name: **beclomethasone 17,21-dipropionate**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Prevention of gastrointestinal graft-versus-host disease*

Sponsor: **Enteron Pharmaceuticals, Inc.**
Address: **1680 Michigan Ave.
Suite 700
Miami FL 33139**

Date Designated: **8/28/2001**
Market Approval Date: **Not currently Approved**

Generic Name: **Beclomethasone dipropionate**

Trade Name: **NONE ASSIGNED**

Designated Indication: *For oral administration in the treatment of intestinal graft-versus-host disease.*

Sponsor: **George B. McDonald, M.D.**
Address: **Fred Hutchinson Cancer Research Center
1100 Fairview Avenue North (SC-113); PO
Seattle WA 98109**

Date Designated: **3/27/1998**
Market Approval Date: **Not currently Approved**

Generic Name: **Benzoate and phenylacetate**

Trade Name: **Ucephan**

Designated Indication: *For adjunctive therapy in the prevention and treatment of hyperammonemia in patients with urea cycle enzymopathy due to carbamylphosphate synthetase, ornithine, transcarbamylase, or argininosuccinate synthetase*

Sponsor: **B. Braun Medical Inc.**
Address: **2525 McGaw Avenue
P.O. Box 19791
Irvine CA 92623**

Date Designated: **1/21/1986**
Market Approval Date: **12/23/1987**

Generic Name: **benzoate/phenylacetate** Trade Name: **Ammonul**
Designated Indication: *For the treatment of acute hyperammonemia and associated encephalopathy in patients with deficiencies in enzymes of the urea cycle.*
Sponsor: **Medicis Pharmaceutical Corp.** Date Designated: **11/22/1993**
Address: **8125 N. Hayden Road** Market Approval Date: **Not currently Approved**
Scottsdale AZ 85258

Generic Name: **Benzophenone-3, octylmethoxycinnamate, avobenzone, titanium dioxide, zinc oxide** Trade Name: **Total Block VL SPF 75**
Designated Indication: *For the prevention of visible light induced skin photosensitivity as a result of porfimer sodium photodynamic therapy*
Sponsor: **Fallien Cosmeceuticals Ltd.** Date Designated: **8/13/2001**
Address: **677 W. Dekalb Pike** Market Approval Date: **Not currently Approved**
King of Prussia PA 19406

Generic Name: **Benzydamine hydrochloride** Trade Name: **Tantum**
Designated Indication: *Prophylactic treatment of oral mucositis resulting from radiation therapy for head and neck cancer.*
Sponsor: **Angelini Pharmaceuticals, Inc.** Date Designated: **5/18/1998**
Address: **70 Grand Avenue** Market Approval Date: **Not currently Approved**
River Edge NJ 07661

Generic Name: **Benzylpenicillin, benzylpenicilloic, benzylpenilloic acid** Trade Name: **Pre-Pen/MDM**
Designated Indication: *Assessing the risk of administering penicillin when it is the preferred drug of choice in adult patients who have previously received penicillin and have a history of clinical sensitivity.*
Sponsor: **Hollister-Stier Laboratories LLC** Date Designated: **9/29/1987**
Address: **PO Box 3145** Market Approval Date: **Not currently Approved**
Spokane WA 99220-3145

Generic Name: **Beractant** Trade Name: **Survanta intratracheal suspension**
Designated Indication: *Treatment of neonatal respiratory distress syndrome.*
Sponsor: **Ross Laboratories** Date Designated: **2/5/1986**
Address: **625 Cleveland Avenue** Market Approval Date: **7/1/1991**
Columbus OH 43215

Generic Name: **Beractant** Trade Name: **Survanta Intratracheal Suspension**
Designated Indication: *Treatment of full-term newborn infants with respiratory failure caused by meconium aspiration syndrome, persistent pulmonary hypertension of the newborn, or pneumonia and sepsis.*
Sponsor: Ross Laboratories Date Designated: 12/20/1993
Address: 625 Cleveland Avenue Market Approval Date: Not currently Approved
Columbus OH 43215

Generic Name: **Beractant** Trade Name: **Survanta intratracheal suspension**
Designated Indication: *Prevention of neonatal respiratory distress syndrome.*
Sponsor: Ross Laboratories Date Designated: 2/5/1986
Address: 625 Cleveland Avenue Market Approval Date: 7/1/1991
Columbus OH 43215

Generic Name: **Beraprost** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of pulmonary arterial hypertension associated with any New York Heart Association classification (Class I, II, III, or IV).*
Sponsor: United Therapeutics Corporation Date Designated: 4/29/1999
Address: 68 T.W. Alexander Drive, PO Box 14186 Market Approval Date: Not currently Approved
Research Triangle Park NC 27709

Generic Name: **Beta alethine** Trade Name: **Betathine**
Designated Indication: *Treatment of multiple myeloma.*
Sponsor: Dovetail Technologies, Inc. Date Designated: 3/24/1997
Address: Bldg. 337, Paint Branch Drive Market Approval Date: Not currently Approved
College Park MD 20742

Generic Name: **Beta alethine** Trade Name: **Betathine**
Designated Indication: *Treatment of metastatic melanoma.*
Sponsor: Dovetail Technologies, Inc. Date Designated: 3/24/1997
Address: Bldg. 337, Paint Branch Drive Market Approval Date: Not currently Approved
College Park MD 20742

Generic **Betaine**
Name:

Trade **Cystadane**
Name:

Designated *Treatment of homocystinuria.*
Indication:

Sponsor: Orphan Medical, Inc.
Address: 13911 Ridgedale Drive
Suite 475
Minnetonka MN 55305

Date Designated: 5/16/1994
Market Approval Date: 10/25/1996

Generic **Bexarotene**
Name:

Trade **Targretin**
Name:

Designated *Treatment of cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one*
Indication: *prior systemic therapy.*

Sponsor: Ligand Pharmaceuticals, Inc.
Address: 10275 Science Center Dr.
San Diego CA 92121

Date Designated: 6/18/1999
Market Approval Date: 12/29/1999

Generic **Bindarit**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of lupus nephritis.*
Indication:

Sponsor: Angelini Pharmaceuticals, Inc.
Address: 70 Grand Avenue
River Edge NJ 07661

Date Designated: 2/3/1998
Market Approval Date: Not currently Approved

Generic **Bis(4-fluorophenyl)phenylacetamide**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of sickle cell disease.*
Indication:

Sponsor: ICAGEN Inc.
Address: Ion Channel Advances
PO Box 14487
Durham NC 27709

Date Designated: 3/2/2000
Market Approval Date: Not currently Approved

Generic **Bispecific antibody 520c9x22**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *For in vivo serotherapy of patients with ovarian cancer.*
Indication:

Sponsor: Medarex, Inc.
Address: 67 Beaver Avenue
Annandale NJ 08801-0953

Date Designated: 10/5/1993
Market Approval Date: Not currently Approved

Generic Name: **Bleomycin** Trade Name: **Blenoxane**
Designated Indication: *Treatment of pancreatic cancer.*
Sponsor: Genetronics, Inc. Date Designated: 2/9/1999
Address: 11199 Sorrento Valley Rd. Market Approval Date: Not currently Approved
San Diego CA 92121-1334

Generic Name: **Bleomycin sulfate** Trade Name: **Blenoxane**
Designated Indication: *Treatment of malignant pleural effusion.*
Sponsor: Bristol-Myers Squibb Pharmaceutical Date Designated: 9/17/1993
Address: P.O. Box 4000 Market Approval Date: 2/20/1996
Princeton NJ 08543

Generic Name: **Bosentan** Trade Name: **Tracleer**
Designated Indication: *Treatment of pulmonary arterial hypertension.*
Sponsor: Actelion Life Sciences Ltd. Date Designated: 10/6/2000
Address: 1840 Gateway Dr. Market Approval Date: 11/20/2001
2nd Floor
San Mateo CA 94404

Generic Name: **Botulinum toxin type A** Trade Name: **Dysport**
Designated Indication: *Treatment of dynamic muscle contractures in pediatric cerebral palsy patients.*
Sponsor: Ipsen Limited Date Designated: 10/20/1999
Address: 1 Bath Rd., Maidenhead Market Approval Date: Not currently Approved
Berkshire SL6 4UH
England GB

Generic Name: **Botulinum toxin type A** Trade Name: **Botox**
Designated Indication: *Treatment of cervical dystonia.*
Sponsor: Allergan, Inc. Date Designated: 8/20/1986
Address: 2525 Dupont Drive Market Approval Date: 12/21/2000
P.O. Box 19534
Irvine CA 92623-9534

Generic Name: **Botulinum toxin type A** Trade Name: **Dysport**
Designated Indication: *Treatment of spasmodic torticollis (cervical dystonia).*
Sponsor: **Ipsen Limited** Date Designated: **8/12/1998**
Address: **1 Bath Road** Market Approval Date: **Not currently Approved**
Maidenhead, Berkshire
U.K. SL6 4UH GB

Generic Name: **Botulinum toxin type A** Trade Name: **Botox**
Designated Indication: *Treatment of dynamic muscle contracture in pediatric cerebral palsy patients.*
Sponsor: **Allergan, Inc.** Date Designated: **12/6/1991**
Address: **2525 Dupont Drive** Market Approval Date: **Not currently Approved**
P.O. Box 19534
Irvine CA 92623-9534

Generic Name: **Botulinum toxin type A** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of synkinetic closure of the eyelid associated with VII cranial nerve aberrant regeneration.*
Sponsor: **Botulinum Toxin Research Associates, Inc.** Date Designated: **9/15/1992**
Address: **1261 Furnace Brook Parkway** Market Approval Date: **Not currently Approved**
Quincy MA 02169

Generic Name: **Botulinum toxin type A** Trade Name: **Dysport**
Designated Indication: *Treatment of essential blepharospasm.*
Sponsor: **Porton International, Inc.** Date Designated: **3/23/1989**
Address: **1155 15th Street, N.W., #315** Market Approval Date: **Not currently Approved**
Washington DC 20005

Generic Name: **Botulinum toxin type A** Trade Name: **Botox**
Designated Indication: *Treatment of strabismus associated with dystonia in adults (patients 12 years of age and above).*
Sponsor: **Allergan, Inc.** Date Designated: **3/22/1984**
Address: **2525 Dupont Drive** Market Approval Date: **12/29/1989**
P.O. Box 19534
Irvine CA 92713

Generic Name: **Botulinum toxin type A**

Trade Name: **Botox**

Designated Indication: *Treatment of blepharospasm associated with dystonia in adults (patients 12 years of age and above).*

Sponsor: **Allergan, Inc.**
Address: **2525 Dupont Drive
P.O. Box 19534
Irvine CA 92713**

Date Designated: **3/22/1984**
Market Approval Date: **12/29/1989**

Generic Name: **Botulinum toxin type B**

Trade Name: **NeuroBloc**

Designated Indication: *Treatment of cervical dystonia.*

Sponsor: **Elan Pharmaceuticals, Inc.**
Address: **800 Gateway Blvd.
South San Francisco CA 94080**

Date Designated: **1/16/1992**
Market Approval Date: **12/8/2000**

Generic Name: **Botulinum toxin type F**

Trade Name: **Dysport**

Designated Indication: *Treatment of spasmodic torticollis (cervical dystonia).*

Sponsor: **Ipsen Limited** (Name: changed from
Address: **Milford MA**

Date Designated: **10/24/1991**
Market Approval Date: **Not currently Approved**

Generic Name: **Botulinum toxin type F**

Trade Name: **Dysport**

Designated Indication: *Treatment of essential blepharospasm.*

Sponsor: **Ipsen Limited** (Name: changed from
Address: **Milford MA**

Date Designated: **12/5/1991**
Market Approval Date: **Not currently Approved**

Generic Name: **Botulism immune globulin**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of infant botulism.*

Sponsor: **California Department of Health Services**
Address: **2151 Berkeley Way
Berkeley CA 94704-1011**

Date Designated: **1/31/1989**
Market Approval Date: **Not currently Approved**

Generic Name: **Bovine colostrum** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of AIDS-related diarrhea.*
Sponsor: **Hastings, Donald DVM** Date Designated: **11/19/1990**
Address: **1030 North Parkview Drive** Market Approval Date: **Not currently Approved**
Bismarck ND 58501

Generic Name: **Bovine immunoglobulin concentrate, Cryptosporidium parvum** Trade Name: **Sporidin-G**
Designated Indication: *Treatment and symptomatic relief of Cryptosporidium parvum infection of the gastrointestinal tract in immunocompromised patients.*
Sponsor: **GalaGen, Inc.** Date Designated: **3/1/1994**
Address: **4001 Lexington Avenue North** Market Approval Date: **Not currently Approved**
Arden Hills MN 55126

Generic Name: **Bovine whey protein concentrate** Trade Name: **Immuno-C**
Designated Indication: *Treatment of cryptosporidiosis caused by the presence of Cryptosporidium parvum in the gastrointestinal tract of patients who are immunodeficient/immunocompromised or immunocompetent.*
Sponsor: **Biomune Systems, Inc.** Date Designated: **9/30/1993**
Address: **540 Arapeen Drive, Suite 202** Market Approval Date: **Not currently Approved**
Salt Lake City UT 84108

Generic Name: **Branched chain amino acids** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of amyotrophic lateral sclerosis.*
Sponsor: **Mount Sinai Medical Center** Date Designated: **12/23/1988**
Address: **One Gustave L. Levy Place** Market Approval Date: **Not currently Approved**
New York NY 10029

Generic Name: **Brimonidine** Trade Name: **Alphagan**
Designated Indication: *Treatment of anterior ischemic optic neuropathy.*
Sponsor: **Allergan, Inc.** Date Designated: **2/7/2000**
Address: **2525 Dupont Dr.** Market Approval Date: **Not currently Approved**
P.O. Box 19534
Irvine CA 92623-9534

Generic Name: **Bromhexine** Trade Name: **Bisolvon**
Designated Indication: *Treatment of mild to moderate keratoconjunctivitis sicca in patients with Sjogren's syndrome.*
Sponsor: **Boehringer Ingelheim Pharmaceuticals, Inc.** Date Designated: **5/15/1989**
Address: **900 Ridgebury Road, Box 368** Market Approval Date: **Not currently Approved**
Ridgefield CT 06877-0368

Generic Name: **Broxuridine** Trade Name: **Broxine/Neomark**
Designated Indication: *Radiation sensitizer in the treatment of primary brain tumors.*
Sponsor: **NeoPharm, Inc.** Date Designated: **9/18/1995**
Address: **225 East Deerpath, Suite 250** Market Approval Date: **Not currently Approved**
Lake Forest IL 60045

Generic Name: **bryostatatin-1** Trade Name: **NONE ASSIGNED**
Designated Indication: *For use in combination with paclitaxel in the treatment of esophageal cancer*
Sponsor: **GPC Biotech, Inc.** Date Designated: **12/3/2001**
Address: **610 Lincoln Street** Market Approval Date: **Not currently Approved**
Waltham MA 02451

Generic Name: **Buffered intrathecal electrolyte/dextrose injection** Trade Name: **Elliotts B Solution**
Designated Indication: *For use as a diluent in the intrathecal administration of methotrexate and cytarabine for the prevention or treatment meningeal leukemia and lymphocytic lymphoma.*
Sponsor: **Orphan Medical, Inc.** Date Designated: **8/24/1994**
Address: **13911 Ridgedale Drive** Market Approval Date: **9/27/1996**
Suite 475
Minnetonka MN 55305

Generic Name: **Buprenorphine hydrochloride** Trade Name: **Subutex**
Designated Indication: *Treatment of opiate addiction in opiate users.*
Sponsor: **Reckitt & Colman Pharmaceuticals, Inc.** Date Designated: **6/15/1994**
Address: **1901 Huguenot Road** Market Approval Date: **Not currently Approved**
Richmond VA 23235

Generic **Buprenorphine in combination with naloxone**
Name:

Trade **Suboxone**
Name:

Designated *Treatment of opiate addiction in opiate users.*
Indication:

Sponsor: **Reckitt & Colman Pharmaceuticals, Inc.**
Address: **1901 Huguenot Road
Richmond VA 23235**

Date Designated: **10/27/1994**
Market Approval Date: **Not currently Approved**

Generic **Busulfan**
Name:

Trade **Spartaject**
Name:

Designated *For use as preparative therapy for malignancies treated with bone marrow transplantation.*
Indication:

Sponsor: **Sparta Pharmaceuticals, Inc.**
Address: **111 Rock Road
Horsham PA 19044-2310**

Date Designated: **4/21/1994**
Market Approval Date: **Not currently Approved**

Generic **Busulfan**
Name:

Trade **Spartaject**
Name:

Designated *Treatment of primary brain malignancies.*
Indication:

Sponsor: **SuperGen, Inc.**
Address: **Two Annabel Lane, Suite 220
San Ramon CA 94583**

Date Designated: **7/7/1997**
Market Approval Date: **Not currently Approved**

Generic **Busulfan**
Name:

Trade **Busulfex**
Name:

Designated *As preparative therapy in the treatment of malignancies with bone marrow transplantation.*
Indication:

Sponsor: **Orphan Medical, Inc.**
Address: **13911 Ridgedale Drive
Suite 250
Minnetonka MN 55305**

Date Designated: **7/28/1994**
Market Approval Date: **2/4/1999**

Generic **Busulfan**
Name:

Trade **Spartajet-Busulfan**
Name:

Designated *Intrathecal therapy for neoplastic meningitis*
Indication:

Sponsor: **SuperGen, Inc.**
Address: **4140 Dublin Boulevard
Dublin CA 94568**

Date Designated: **3/5/2001**
Market Approval Date: **Not currently Approved**

Generic Name: **Butyrylcholinesterase** Trade Name: **NONE ASSIGNED**
Designated Indication: *For the reduction and clearance of toxic blood levels of cocaine encountered during a drug overdose.*
Sponsor: Shire Laboratories Inc. Date Designated: 3/25/1992
Address: 1550 East Gude Drive Market Approval Date: Not currently Approved
Rockville MD 20850

Generic Name: **Butyrylcholinesterase** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of post-surgical apnea.*
Sponsor: Shire Laboratories Inc. Date Designated: 9/30/1992
Address: 1550 East Gude Drive Market Approval Date: Not currently Approved
Rockville MD 20850

Generic Name: **BW 12C** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of sickle cell disease.*
Sponsor: Burroughs Wellcome Company Date Designated: 10/23/1987
Address: 3030 Cornwallis Road Market Approval Date: Not currently Approved
P.O. Box 12700
Research Triangle Pk NC 27709

Generic Name: **C1 esterase inhibitor (human)** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment and prevention of angioedema caused by C1-esterase inhibitor deficiency.*
Sponsor: Alpha Therapeutic Corporation Date Designated: 8/21/1996
Address: 5555 Valley Boulevard Market Approval Date: Not currently Approved
Los Angeles CA 90032

Generic Name: **C1-esterase-inhibitor, human, pasteurized** Trade Name: **Beriner P**
Designated Indication: *Prevention and/or treatment of acute attacks of hereditary angioedema.*
Sponsor: Aventis Behring L.L.C. Date Designated: 10/16/1992
Address: 1020 First Ave. Market Approval Date: Not currently Approved
PO Box 61501
King of Prussia PA 19406-0901

Generic **C1-inhibitor** Trade C1-inhibitor (human) vapor heated, Immuno
Name: Name:
Designated *Treatment of acute attacks of angioedema.*
Indication:
Sponsor: Baxter Healthcare Corp. Date Designated: 8/30/1990
Address: Hyland Division (Baxter Hyland) Market Approval Date: Not currently Approved
550 North Brand Blvd.
Glendale CA 91203

Generic **C1-inhibitor** Trade C1-inhibitor (human) vapor heated, Immuno
Name: Name:
Designated *Prevention of acute attacks of angioedema, including short-term prophylaxis for patients requiring dental or other*
Indication: *surgical procedures.*
Sponsor: Baxter Healthcare Corp. Date Designated: 8/30/1990
Address: Hyland Division (Baxter Hyland) Market Approval Date: Not currently Approved
550 North Brand Blvd.
Glendale CA 91203

Generic **Caffeine** Trade Cafcit
Name: Name:
Designated *Treatment of apnea of prematurity.*
Indication:
Sponsor: O.P.R. Development, L.P. Date Designated: 9/20/1988
Address: 1501 Wakarusa Drive Market Approval Date: 9/21/1999
Lawrence KS 66047

Generic **Calcitonin-human for injection** Trade Cibacalcin
Name: Name:
Designated *Treatment of symptomatic Paget's disease (osteitis deformans).*
Indication:
Sponsor: Novartis Pharmaceutical Corporation Date Designated: 1/20/1987
Address: 59 Route 10 Market Approval Date: 10/31/1986
East Hanover NJ 07936

Generic **Calcium acetate** Trade NONE ASSIGNED
Name: Name:
Designated *Treatment of hyperphosphatemia in end stage renal disease.*
Indication:
Sponsor: Pharmedic Company Date Designated: 6/27/1989
Address: 28101 Ballard Road, Suite F Market Approval Date: Not currently Approved
Lake Forest IL 60045

Generic Name: **Calcium acetate**

Trade Name: **Phos-Lo**

Designated Indication: *Treatment of hyperphosphatemia in end stage renal failure.*

Sponsor: **Braintree Laboratories**
Address: **60 Columbian Street**
P.O. Box 361
Braintree MA 02184

Date Designated: **12/22/1988**
Market Approval Date: **12/10/1990**

Generic Name: **Calcium carbonate**

Trade Name: **R & D calcium carbonate/600**

Designated Indication: *Treatment of hyperphosphatemia in patients with end stage renal disease.*

Sponsor: **R & D Laboratories, Inc.**
Address: **4204 Glencoe Avenue**
Marina Del Rey CA 90292

Date Designated: **6/6/1990**
Market Approval Date: **Not currently Approved**

Generic Name: **Calcium gluconate**

Trade Name: **Calgonate**

Designated Indication: *For use as a wash for hydrofluoric acid spills on human skin.*

Sponsor: **Calgonate Corp.**
Address: **190 Commerce Drive**
Warwick RI 02886

Date Designated: **11/20/1997**
Market Approval Date: **Not currently Approved**

Generic Name: **Calcium gluconate gel**

Trade Name: **H-F Gel**

Designated Indication: *For use in the emergency topical treatment of hydrogen fluoride (hydrofluoric acid) burns.*

Sponsor: **LTR Pharmaceuticals, Inc.**
Address: **145 Sakonnet Blvd.**
Narragansett RI 02882

Date Designated: **5/21/1991**
Market Approval Date: **Not currently Approved**

Generic Name: **Calcium gluconate gel 2.5%**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Emergency topical treatment of hydrogen fluoride (hydrofluoric acid) burns.*

Sponsor: **Paddock Laboratories, Inc.**
Address: **3940 Quebec Avenue North**
Minneapolis MN 55427

Date Designated: **9/10/1990**
Market Approval Date: **Not currently Approved**

Generic Name: **Calfactant**

Trade Name: **Infasurf**

Designated Indication: *Acute respiratory distress syndrome (ARDS)*

Sponsor: **ONY, Inc.**
Address: **Baird Research Park
1576 Sweet Home Road
Amherst NY 14228**

Date Designated: **9/5/2000**
Market Approval Date: **Not currently Approved**

Generic Name: **Carbamylglutamic acid**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of N-acetylglutamate synthetase deficiency.*

Sponsor: **Orphan Europe**
Address: **Immeuble "Le Guillaumet"
60, avenue du General de Gaulle - Cedex 70
92046 Paris La Defense FR**

Date Designated: **1/20/1998**
Market Approval Date: **Not currently Approved**

Generic Name: **Carmustine**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of intracranial malignancies.*

Sponsor: **Direct Therapeutics, Inc.**
Address: **1001 Bayhill Dr., Suite 100
San Bruno CA 94066**

Date Designated: **7/3/2000**
Market Approval Date: **Not currently Approved**

Generic Name: **Cascara sagrada fluid extract**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of oral drug overdosage to speed lower bowel evacuation.*

Sponsor: **Intramed Corporation**
Address: **102 Tremont Way
Augusta GA 30907**

Date Designated: **3/21/1989**
Market Approval Date: **Not currently Approved**

Generic Name: **CDP571** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of Crohn's disease.*
Sponsor: Celltech Chiroscience Limited Date Designated: 12/11/1997
Address: 216 Bath Road Market Approval Date: Not currently Approved
Slough SL1 4EN
Berkshire UK

Generic Name: **Centruroides immune F(ab)2** Trade Name: **Alacramyn**
Designated Indication: *Treatment of scorpion envenomations requiring medical attention.*
Sponsor: Silanes Laboratories S.A. de C.V. Date Designated: 6/12/2000
Address: Amores #1034 Col Del Valle Market Approval Date: Not currently Approved
C.P. 03100 Mexico D.F.

Generic Name: **Ceramide trihexosidase/alpha-galactosidase A** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of Fabry's disease.*
Sponsor: Genzyme Corporation Date Designated: 1/19/1988
Address: One Kendall Square Market Approval Date: Not currently Approved
Cambridge MA 02139-1562

Generic Name: **Cetuximab** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of squamous cell cancer of the head and neck in patients who express epidermal growth factor receptor.*
Sponsor: ImClone Systems Incorporated Date Designated: 7/3/2000
Address: Branchburg Corporate Center Market Approval Date: Not currently Approved
22 Chubb Way
Somerville NJ 08876

Generic Name: **Chenodiol** Trade Name: **Chenix**
Designated Indication: *For patients with radiolucent stones in well opacifying gallbladders, in whom elective surgery would be undertaken except for the presence of increased surgical risk due to systemic disease or age.*
Sponsor: Solvay Date Designated: 9/21/1984
Address: 901 Sawyer Road Market Approval Date: 7/28/1983
Marietta GA 30062

Generic Name: **Chimeric (human-murine) G250 IgG monoclonal antibody** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of renal cell carcinoma.*
Sponsor: **Wilex Biotechnology GmbH** Date Designated: **7/24/2000**
Address: **Grillparzerstrasse 10B** Market Approval Date: **Not currently Approved**
81675 Munich
Germany DE

Generic Name: **Chimeric, humanized monoclonal antibody to staphylococcus** Trade Name: **NONE ASSIGNED**
Designated Indication: *Prophylaxis of Staphylococcus epidermidis sepsis in low birth weight (1500 grams or less) infants.*
Sponsor: **Biosynexus, Inc.** Date Designated: **8/3/2000**
Address: **9610 Medical Center Drive** Market Approval Date: **Not currently Approved**
Suite 100
Rockville MD 20850

Generic Name: **Chlorhexidine gluconate mouthrinse** Trade Name: **Peridex**
Designated Indication: *For use in the amelioration of oral mucositis associated with cytoreductive therapy used in conditioning patients for bone marrow transplantation therapy.*
Sponsor: **Procter & Gamble Company** Date Designated: **8/18/1986**
Address: **Sharon Wood Technical Center** Market Approval Date: **Not currently Approved**
11370 Reed Hartman Highway
Cincinnati OH 45241

Generic Name: **Choline chloride** Trade Name: **Intrachol**
Designated Indication: *Treatment of choline deficiency, specifically the choline deficiency, hepatic steatosis, and cholestasis, associated with long-term parenteral nutrition.*
Sponsor: **Orphan Medical, Inc.** Date Designated: **2/10/1994**
Address: **13911 Ridgedale Drive** Market Approval Date: **Not currently Approved**
Suite 250
Minnetonka MN 55305

Generic Name: **Chondrocyte-alginate gel suspension** Trade Name: **NONE ASSIGNED**
Designated Indication: *For use in correcting vesicoureteral reflux in the pediatric population.*
Sponsor: **Curis, Inc.** Date Designated: **12/1/1997**
Address: **61 Moulton Street** Market Approval Date: **Not currently Approved**
Cambridge MA 02138

Generic Name: **Ciliary neurotrophic factor**

Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of amyotrophic lateral sclerosis.*

Sponsor: Regeneron Pharmaceuticals Inc
Address: 777 Old Saw Mill River Road
Tarrytown NY 10591

Date Designated: 1/30/1992
Market Approval Date: Not currently Approved

Generic Name: **Cisplatin/epinephrine**

Trade Name: IntraDose

Designated Indication: *Treatment of metastatic malignant melanoma.*

Sponsor: Matrix Pharmaceutical, Inc.
Address: 34700 Campus Drive
Fremont CA 94555-3612

Date Designated: 9/7/2000
Market Approval Date: Not currently Approved

Generic Name: **Cisplatin/epinephrine**

Trade Name: IntraDose

Designated Indication: *Treatment of squamous cell carcinoma of the head and neck.*

Sponsor: Matrix Pharmaceutical, Inc.
Address: 34700 Campus Drive
Fremont CA 94555-3612

Date Designated: 4/3/2000
Market Approval Date: Not currently Approved

Generic Name: **Citric acid, glucono-delta-lactone and magnesium carbonate**

Trade Name: Renacidin Irrigation

Designated Indication: *Treatment of renal and bladder calculi of the apatite or struvite variety.*

Sponsor: United-Guardian, Inc.
Address: P.O. Box 2500
Smithtown NY 11787

Date Designated: 8/28/1989
Market Approval Date: 10/2/1990

Generic Name: **Cladribine**

Trade Name: Leustatin Injection

Designated Indication: *Treatment of chronic lymphocytic leukemia.*

Sponsor: R. W. Johnson Pharmaceutical Research
Address: Route 202, P.O. Box 300
Raritan NJ 08869-0602

Date Designated: 12/31/1990
Market Approval Date: Not currently Approved

Generic Name: **Cladribine** Trade Name: **Leustatin Injection**
Designated Indication: *Treatment of non-Hodgkin's lymphoma.*
Sponsor: R. W. Johnson Pharmaceutical Research Date Designated: 4/19/1993
Address: Route 202 South, P.O. Box 300 Market Approval Date: Not currently Approved
Raritan NJ 08869-0602

Generic Name: **Cladribine** Trade Name: **Mylinax**
Designated Indication: *Treatment of the chronic progressive form of multiple sclerosis.*
Sponsor: R. W. Johnson Pharmaceutical Research Date Designated: 4/19/1994
Address: Route 202 Market Approval Date: Not currently Approved
PO Box 300
Raritan NJ 08869-0602

Generic Name: **Cladribine** Trade Name: **Leustatin Injection**
Designated Indication: *Treatment of hairy cell leukemia.*
Sponsor: R. W. Johnson Pharmaceutical Research Date Designated: 11/15/1990
Address: Route 202, P.O. Box 300 Market Approval Date: 2/26/1993
Raritan NJ 08869

Generic Name: **Cladribine** Trade Name: **Leustatin**
Designated Indication: *Treatment of acute myeloid leukemia.*
Sponsor: R. W. Johnson Pharmaceutical Research Date Designated: 7/20/1990
Address: Route 202 Market Approval Date: Not currently Approved
P.O. Box 300
Raritan NJ 08869

Generic Name: **Clindamycin** Trade Name: **Cleocin**
Designated Indication: *Treatment of *Pneumocystis carinii* pneumonia associated with AIDS patients.*
Sponsor: Pharmacia & Upjohn Date Designated: 10/28/1988
Address: 7000 Portage Road Market Approval Date: Not currently Approved
Unit 0633-298-113
Kalamazoo MI 49001-0199

Generic Name: **Clindamycin**

Trade Name: **Cleocin**

Designated Indication: *Prevention of Pneumocystis carinii pneumonia in AIDS patients.*

Sponsor: Pharmacia & Upjohn
Address: 7000 Portage Road
Unit 0633-298-113
Kalamazoo MI 49001-0199

Date Designated: 10/28/1988
Market Approval Date: Not currently Approved

Generic Name: **Clofazimine**

Trade Name: **Lamprene**

Designated Indication: *Treatment of lepromatous leprosy, including dapsone-resistant lepromatous leprosy and lepromatous leprosy complicated by erythema nodosum leprosum.*

Sponsor: Novartis Pharmaceutical Corporation
Address: 59 Route 10
East Hanover NJ 07936

Date Designated: 6/11/1984
Market Approval Date: 12/15/1986

Generic Name: **Clonazepam**

Trade Name: **Klonopin**

Designated Indication: *Treatment of hyperekplexia (startle disease).*

Sponsor: Hoffmann-La Roche, Inc.
Address: 340 Kingsland Street
Nutley NJ 07110

Date Designated: 8/4/1994
Market Approval Date: Not currently Approved

Generic Name: **Clonidine**

Trade Name: **Duraclon**

Designated Indication: *For continuous epidural administration as adjunctive therapy with intraspinal opiates for the treatment of pain in cancer patients tolerant to, or unresponsive to, intraspinal opiates.*

Sponsor: Roxane Laboratories, Inc.
Address: PO Box 16532
Columbus OH 43216-6532

Date Designated: 1/24/1989
Market Approval Date: 10/2/1996

Generic Name: **Clostridial collagenase**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of advanced (involutional or residual stage) Dupuytren's disease.*

Sponsor: Hurst, L. M.D. & Badalamente, M. Ph.D.
Address: State University of New York at Stony Brook
School of Medicine, Health Sciences Center
Stony Brook NY 11794-8181

Date Designated: 5/23/1996
Market Approval Date: Not currently Approved

Generic Name: **Clotrimazole**

Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of sickle cell disease.*

Sponsor: Brugnara, Carlo M.D.
Address: The Children's Hospital
300 Longwood Avenue, Bader 760
Boston MA 02115

Date Designated: 4/24/1995
Market Approval Date: Not currently Approved

Generic Name: **Coagulation factor IX**

Trade Name: Mononine

Designated Indication: *Replacement treatment and prophylaxis of the hemorrhagic complications of hemophilia B.*

Sponsor: Armour Pharmaceutical Company
Address: 500 Arcola Road, P.O. Box 1200
Collegeville PA 19426

Date Designated: 6/27/1989
Market Approval Date: 8/20/1992

Generic Name: **Coagulation Factor IX (human)**

Trade Name: AlphaNine

Designated Indication: *For use as replacement therapy in patients with hemophilia B for the prevention and control of bleeding episodes, and during surgery to correct defective hemostasis.*

Sponsor: Alpha Therapeutic Corporation
Address: 5555 Valley Boulevard
Los Angeles CA 90032

Date Designated: 7/5/1990
Market Approval Date: 12/31/1990

Generic Name: **Coagulation Factor IX (recombinant)**

Trade Name: BeneFix

Designated Indication: *Treatment of hemophilia B.*

Sponsor: Genetics Institute, Inc.
Address: 87 Cambridge Park Drive
Cambridge MA 02140

Date Designated: 10/3/1994
Market Approval Date: 2/11/1997

Generic Name: **Coagulation factor VIIa (recombinant)**

Trade Name: NovoSeven

Designated Indication: *Treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX.*

Sponsor: Novo Nordisk Pharmaceuticals, Inc.
Address: 100 Overlook Center
Suite 200
Princeton NJ 08540-7810

Date Designated: 6/6/1988
Market Approval Date: 3/25/1999

Generic Name: **Coenzyme Q10**

Trade Name: **NONE ASSIGNED**

Designated Indication: *For the treatment of Huntington's disease*

Sponsor: **Vitaline Corporation**
Address: **385 Williamson Way
Ashland OR 97520**

Date Designated: **3/5/2001**
Market Approval Date: **Not currently Approved**

Generic Name: **Colfosceril palmitate, cetyl alcohol, tyloxapol**

Trade Name: **Exosurf**

Designated Indication: *Treatment of adult respiratory distress syndrome.*

Sponsor: **Glaxo Wellcome Research and Development**
Address: **5 Moore Drive
P.O. Box 13398
Research Triangle Park NC 27709**

Date Designated: **1/11/1993**
Market Approval Date: **Not currently Approved**

Generic Name: **Colfosceril palmitate, cetyl alcohol, tyloxapol**

Trade Name: **Exosurf Neonatal for Intratracheal Suspension**

Designated Indication: *Prevention of hyaline membrane disease, also known as respiratory distress syndrome, in infants born at 32 weeks gestation or less.*

Sponsor: **Glaxo Wellcome Inc.**
Address: **5 Moore Drive
Research Triangle Park NC 27709**

Date Designated: **10/20/1989**
Market Approval Date: **8/2/1990**

Generic Name: **Colfosceril palmitate, cetyl alcohol, tyloxapol**

Trade Name: **Exosurf Neonatal for Intratracheal Suspension**

Designated Indication: *Treatment of established hyaline membrane disease at all gestational ages.*

Sponsor: **Glaxo Wellcome Inc.**
Address: **5 Moore Drive
Research Triangle Park NC 27709**

Date Designated: **10/20/1989**
Market Approval Date: **8/2/1990**

Generic Name: **Collagenase (lyophilized) for injection**

Trade Name: **Plaquease**

Designated Indication: *Treatment of Peyronie's disease.*

Sponsor: **Advance Biofactures Corporation**
Address: **35 Wilbur Street
Lynbrook NY 11563-2358**

Date Designated: **3/12/1996**
Market Approval Date: **Not currently Approved**

Generic Name: **conjugate of human transferrin and a mutant diphtheria toxin (CRM 107)** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of malignant tumors of the central nervous system*
Sponsor: **INTELLigene Expressions Inc.** Date Designated: **12/3/2001**
Address: **1938-94 St.** Market Approval Date: **Not currently Approved**
Edmonton, AB T6N 1J3

Generic Name: **Corticotropin-releasing factor, human** Trade Name: **Acthrel**
Designated Indication: *For use in differentiating pituitary and ectopic production of ACTH in patients with ACTH-dependent Cushing's syndrome.*
Sponsor: **Ferring Laboratories, Inc.** Date Designated: **11/24/1989**
Address: **400 Rella Boulevard, Suite 201** Market Approval Date: **5/23/1996**
Suffern NY 10901

Generic Name: **Corticotropin-releasing factor, human** Trade Name: **Xerecept**
Designated Indication: *Treatment of peritumoral brain edema.*
Sponsor: **Neurobiological Technologies, Inc.** Date Designated: **4/6/1998**
Address: **1387 Marina Way South** Market Approval Date: **Not currently Approved**
Richmond CA 94804

Generic Name: **Coumarin** Trade Name: **Onkolox**
Designated Indication: *Treatment of renal cell carcinoma.*
Sponsor: **Drossapharm LTD** Date Designated: **12/22/1994**
Address: **4002 Basel** Market Approval Date: **Not currently Approved**
Switzerland CH

Generic Name: **Cromolyn sodium** Trade Name: **Gastrocrom**
Designated Indication: *Treatment of mastocytosis.*
Sponsor: **Fisons Corporation** Date Designated: **3/8/1984**
Address: **755 Jefferson Rd** Market Approval Date: **12/22/1989**
P.O. Box 1710
Rochester NY 14603

Generic Name: **Cromolyn sodium 4% ophthalmic solution**

Trade Name: **Opticrom 4% ophthalmic solution**

Designated Indication: *Treatment of vernal keratoconjunctivitis.*

Sponsor: **Fisons Corporation**
Address: **755 Jefferson Rd.
P.O. Box 1710
Rochester NY 14603**

Date Designated: **7/24/1985**
Market Approval Date: **10/3/1984**

Generic Name: **Cryptosporidium hyperimmune bovine colostrum IgG concentrate**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of diarrhea in AIDS patients caused by infection with Cryptosporidium parvum.*

Sponsor: **ImmuCell Corporation**
Address: **56 Evergreen Drive
Portland ME 04103**

Date Designated: **12/30/1991**
Market Approval Date: **Not currently Approved**

Generic Name: **CT-2584 mesylate**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of adult soft tissue sarcoma.*

Sponsor: **Cell Therapeutics, Inc.**
Address: **201 Elliott Ave. West
Suite 400
Seattle WA 98119**

Date Designated: **4/16/1999**
Market Approval Date: **Not currently Approved**

Generic Name: **CT-2584 mesylate**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of malignant mesothelioma.*

Sponsor: **Cell Therapeutics, Inc.**
Address: **201 Elliott Ave. West
Seattle WA 98119**

Date Designated: **4/16/1999**
Market Approval Date: **Not currently Approved**

Generic Name: **CY-1503**

Trade Name: **Cylexin**

Designated Indication: *Treatment of neonates and infants undergoing cardiopulmonary bypass during surgical repair of congenital heart lesions.*

Sponsor: **Cytel Corporation**
Address: **3525 John Hopkins Court
San Diego CA 92121**

Date Designated: **7/18/1997**
Market Approval Date: **Not currently Approved**

Generic Name: **CY-1503** Trade Name: **Cylexin**
Designated Indication: *Treatment of post-ischemic pulmonary reperfusion edema following surgical treatment for chronic thromboembolic pulmonary hypertension.*
Sponsor: **Cytel Corporation** Date Designated: **12/22/1993**
Address: **3525 John Hopkins Court** Market Approval Date: **Not currently Approved**
San Diego CA 92121

Generic Name: **CY-1899** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of chronic active hepatitis B infection in HLA-A2 positive patients.*
Sponsor: **Cytel Corporation** Date Designated: **3/16/1994**
Address: **3525 John Hopkins Court** Market Approval Date: **Not currently Approved**
San Diego CA 92121

Generic Name: **Cyclosporine 2% ophthalmic ointment** Trade Name: **NONE ASSIGNED**
Designated Indication: *For use in corneal melting syndromes of known or presumed immunologic etiopathogenesis, including Mooren's ulcer.*
Sponsor: **Allergan, Inc.** Date Designated: **8/1/1991**
Address: **2525 Dupont Drive** Market Approval Date: **Not currently Approved**
P.O. Box 19534
Irvine CA 92623-9534

Generic Name: **Cyclosporine 2% ophthalmic ointment** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of patients at high risk of graft rejection following penetrating keratoplasty.*
Sponsor: **Allergan, Inc.** Date Designated: **8/1/1991**
Address: **2525 Dupont Drive** Market Approval Date: **Not currently Approved**
P.O. Box 19534
Irvine CA 92623-9534

Generic Name: **Cyclosporine in combination with omega-3 polyunsaturated fatty acids** Trade Name: **NONE ASSIGNED**
Designated Indication: *Prevention of solid organ graft rejection.*
Sponsor: **RTP Pharma Corporation** Date Designated: **12/6/2000**
Address: **200 Westpark Corporate Center** Market Approval Date: **Not currently Approved**
4364 South Alston Avenue
Durham NC 27713-2280

Generic Name: **Cyclosporine ophthalmic** Trade Name: **Optimmune**
Designated Indication: *Treatment of severe keratoconjunctivitis sicca associated with Sjogren's syndrome.*
Sponsor: University Of Georgia Date Designated: 11/9/1988
Address: College Of Veterinary Medicine Market Approval Date: Not currently Approved
Department of Small Animal Medicine
Athens GA 30602

Generic Name: **Cysteamine** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of nephropathic cystinosis.*
Sponsor: Thoene, Jess G., M.D. Date Designated: 5/1/1986
Address: University of Michigan Medical School Market Approval Date: Not currently Approved
300 NIB, 1192 SE
Ann Arbor MI 48109-0408

Generic Name: **Cysteamine** Trade Name: **Cystagon**
Designated Indication: *Treatment of nephropathic cystinosis.*
Sponsor: Mylan Laboratories, Inc. Date Designated: 1/25/1991
Address: 781 Chestnut Ridge Road Market Approval Date: 8/15/1994
P.O. Box 4310
Morgantown WV 26504

Generic Name: **Cysteamine hydrochloride** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of corneal cystine crystal accumulation in cystinosis patients.*
Sponsor: Sigma-Tau Pharmaceuticals, Inc. Date Designated: 8/19/1997
Address: 800 South Frederick Avenue Market Approval Date: Not currently Approved
Gaithersburg MD 20877

Generic Name: **Cystic fibrosis gene therapy** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of cystic fibrosis.*
Sponsor: Genzyme Corporation Date Designated: 6/30/1992
Address: One Mountain Rd. Market Approval Date: Not currently Approved
P.O. Box 9322
Framingham MA 01701-9322

Generic Name: **Cystic fibrosis Tr gene therapy (recombinant adenovirus)** Trade Name: **AdGVCFTR.10**
Designated Indication: *Treatment of cystic fibrosis.*
Sponsor: **GenVec, Inc.** Date Designated: **3/9/1995**
Address: **12111 Parklawn Drive** Market Approval Date: **Not currently Approved**
Rockville MD 20852

Generic Name: **Cystic fibrosis transmembrane conductance regulator gene** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of cystic fibrosis.*
Sponsor: **Genetic Therapy, Inc.** Date Designated: **1/8/1993**
Address: **938 Clopper Road** Market Approval Date: **Not currently Approved**
Gaithersburg MD 20878

Generic Name: **Cytarabine liposomal** Trade Name: **DepoCyt**
Designated Indication: *Treatment of neoplastic meningitis.*
Sponsor: **DepoTech Corporation** Date Designated: **6/2/1993**
Address: **10450 Science Center Drive** Market Approval Date: **4/1/1999**
San Diego CA 92121

Generic Name: **Cytomegalovirus immune globulin (human)** Trade Name: **CytoGam**
Designated Indication: *Prevention or attenuation of primary cytomegalovirus disease in immunosuppressed recipients of organ transplants.*
Sponsor: **Massachusetts Public Health Biologic** Date Designated: **8/3/1987**
Address: **305 South Street** Market Approval Date: **12/4/1998**
Boston MA 02130-3597

Generic Name: **Cytomegalovirus immune globulin intravenous (human)** Trade Name: **NONE ASSIGNED**
Designated Indication: *For use in conjunction with ganciclovir sodium for the treatment of cytomegalovirus pneumonia in bone marrow transplant patients.*
Sponsor: **Bayer Corporation** Date Designated: **1/28/1991**
Address: **Pharmaceutical Division, Biological Products** Market Approval Date: **Not currently Approved**
400 Morgan Lane
New Haven CT 06516

Generic **Daclizumab**
Name:

Trade **Zenapax**
Name:

Designated *Prevention of acute renal allograft rejection.*
Indication:

Sponsor: Hoffmann-La Roche, Inc.
Address: 340 Kingsland Street
Nutley NJ 07110

Date Designated: 3/5/1993
Market Approval Date: 12/10/1997

Generic **Dapsone**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Prophylaxis of toxoplasmosis in severely immunocompromised patients with CD4 counts below 100.*
Indication:

Sponsor: Jacobus Pharmaceutical Company, Inc.
Address: 37 Cleveland Lane
P.O. Box 5290
Princeton NJ 08540

Date Designated: 11/7/1994
Market Approval Date: Not currently Approved

Generic **Dapsone USP**
Name:

Trade **Dapsone**
Name:

Designated *For the combination treatment of *Pneumocystis carinii* pneumonia in conjunction with trimethoprim.*
Indication:

Sponsor: Jacobus Pharmaceutical Company
Address: 37 Cleveland Lane
P.O. Box 5290
Princeton NJ 08540

Date Designated: 1/8/1992
Market Approval Date: Not currently Approved

Generic **Dapsone USP**
Name:

Trade **Dapsone**
Name:

Designated *Prophylaxis for *Pneumocystis carinii* pneumonia.*
Indication:

Sponsor: Jacobus Pharmaceutical Company
Address: 37 Cleveland Lane
P.O. Box 5290
Princeton NJ 08540

Date Designated: 12/24/1991
Market Approval Date: Not currently Approved

Generic **Daunorubicin citrate liposome injection**
Name:

Trade **DaunoXome**
Name:

Designated *Treatment of patients with advanced HIV-associated Kaposi's sarcoma.*
Indication:

Sponsor: NeXstar Pharmaceuticals, Inc.
Address: 650 Cliffside Drive
San Dimas CA 91773

Date Designated: 5/14/1993
Market Approval Date: 4/8/1996

Generic **Decitabine**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of myelodysplastic syndromes.*
Indication:

Sponsor: SuperGen, Inc.
Address: 4140 Dublin Blvd.
Suite 200
Dublin CA 94568

Date Designated: 3/8/1999
Market Approval Date: Not currently Approved

Generic **Decitabine**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of chronic myelogenous leukemia.*
Indication:

Sponsor: SuperGen, Inc.
Address: 4140 Dublin Blvd.
Suite 200
Dublin CA 94568

Date Designated: 3/8/1999
Market Approval Date: Not currently Approved

Generic **deferiprone**
Name:

Trade **Ferriprox**
Name:

Designated *Treatment of iron overload in patients with hematologic disorders requiring chronic transfusion therapy*
Indication:

Sponsor: Apotex Research Inc.
Address: 150 Signet Drive
Toronto, Canada M9L 1T9

Date Designated: 12/12/2001
Market Approval Date: Not currently Approved

Generic **Defibrotide**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of thrombotic thrombocytopenic purpura.*
Indication:

Sponsor: Crinos International
Address: Via Belvedere 1
Villa Guardia, Italy 22079

Date Designated: 7/5/1985
Market Approval Date: Not currently Approved

Generic **Dehydroepiandrosterone**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of systemic lupus erythematosus (SLE) and the reduction in the use of steroids in steroid-dependent SLE*
Indication: *patients.*

Sponsor: Genelabs Technologies, Inc.
Address: 505 Penobscot Drive
Redwood City CA 94063

Date Designated: 7/13/1994
Market Approval Date: Not currently Approved

Generic Name: **Dehydroepiandrosterone sulfate sodium** Trade Name: **NONE ASSIGNED**
Designated Indication: *To accelerate the re-epithelialization of donor sites in those hospitalized burn patients who must undergo autologous skin grafting.*
Sponsor: **Pharmadigm, Inc.** Date Designated: **1/28/1997**
Address: **2401 Foothill Drive** Market Approval Date: **Not currently Approved**
Salt Lake City UT 84109-1405

Generic Name: **Dehydroepiandrosterone sulfate sodium** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of serious burns requiring hospitalization.*
Sponsor: **Pharmadigm, Inc.** Date Designated: **1/29/1997**
Address: **2401 Foothill Drive** Market Approval Date: **Not currently Approved**
Salt Lake City UT 84109-1405

Generic Name: **Denileukin diftitox** Trade Name: **Ontak**
Designated Indication: *Treatment of patients with persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD25 component of the IL-2 receptor.*
Sponsor: **Seragen, Inc.** Date Designated: **8/21/1996**
Address: **97 South Street** Market Approval Date: **2/5/1999**
Hopkinton MA 01748

Generic Name: **Deoxyribose, phosphorothioate** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of advanced malignant melanoma (Stages II, III, IV).*
Sponsor: **Genta, Inc.** Date Designated: **7/31/2000**
Address: **99 Hayden Ave., Suite 200** Market Approval Date: **Not currently Approved**
Lexington MA 02421-7966

Generic Name: **Deslorelin** Trade Name: **Somagard**
Designated Indication: *Treatment of central precocious puberty.*
Sponsor: **Roberts Pharmaceutical Corp.** Date Designated: **11/5/1987**
Address: **Meridian Center II** Market Approval Date: **Not currently Approved**
Four Industrial Way West
Eatontown NJ 07724-2274

Generic **Desmopressin acetate**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of mild hemophilia A and von Willebrand's disease.*
Indication:

Sponsor: **Aventis Behring L.L.C.**
Address: **1020 First Avenue**
PO Box 61501
King of Prussia PA 19406-0901

Date Designated: **1/22/1991**
Market Approval Date: **3/7/1994**

Generic **Dexamethasone**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *For use in posterior segment drug delivery system in the treatment of idiopathic intermediate uveitis.*
Indication:

Sponsor: **Oculex Pharmaceuticals, Inc.**
Address: **639 N. Pastoria Avenue**
Sunnyvale CA 94086-2917

Date Designated: **9/11/1998**
Market Approval Date: **Not currently Approved**

Generic **Dexrazoxane**
Name:

Trade **Zinecard**
Name:

Designated *For the prevention of cardiomyopathy associated with doxorubicin administration.*
Indication:

Sponsor: **Pharmacia & Upjohn**
Address: **7000 Portage Road**
Kalamazoo MI 49001-0199

Date Designated: **12/17/1991**
Market Approval Date: **5/26/1995**

Generic **Dextran 70**
Name:

Trade **Dehydrex**
Name:

Designated *Treatment of recurrent corneal erosion unresponsive to conventional therapy.*
Indication:

Sponsor: **Holles Laboratories, Inc.**
Address: **30 Forest Notch**
Cohasset MA 02025

Date Designated: **3/5/1990**
Market Approval Date: **Not currently Approved**

Generic **Dextran and deferoxamine**
Name:

Trade **Bio-Rescue**
Name:

Designated *Treatment of acute iron poisoning.*
Indication:

Sponsor: **Biomedical Frontiers, Inc.**
Address: **1095 10th Avenue S.E.**
Minneapolis MN 55414

Date Designated: **3/8/1991**
Market Approval Date: **Not currently Approved**

Generic **Dextran sulfate (inhaled, aerosolized)**
Name:

Trade Name: Uendex

Designated *For use as an adjunct to the treatment of cystic fibrosis.*
Indication:

Sponsor: Kennedy & Hoidal, M.D.'s
Address: University Of Utah Medical Center
50 North Medical Drive, Room 4R240
Salt Lake City UT 84132

Date Designated: 10/5/1990
Market Approval Date: Not currently Approved

Generic **Dextran sulfate sodium**
Name:

Trade Name: NONE ASSIGNED

Designated *Treatment of aquired immunodeficiency syndrome.*
Indication:

Sponsor: Ueno Fine Chemicals Industry, Ltd.
Address: 2-31 Koraibashi, Higashi-ku
Osaka 541, Japan

Date Designated: 11/19/1987
Market Approval Date: Not currently Approved

Generic **DHA-paclitaxel**
Name:

Trade Name: Taxoprexin

Designated *Treatment of pancreatic cancer*
Indication:

Sponsor: Protarga, Inc.
Address: 2200 Renaissance Blvd.
Suite 450
King of Prussia PA 19406

Date Designated: 9/25/2001
Market Approval Date: Not currently Approved

Generic **Dianeal peritoneal dialysis solution with 1.1% amino acids**
Name:

Trade Name: Nutrineal (Peritoneal Dialysis Solution with 1.1% Amino Acid)

Designated *For use as a nutritional supplement for the treatment of malnourishment in patients undergoing continuous ambulatory peritoneal dialysis.*
Indication:

Sponsor: Baxter Healthcare Corporation
Address: 1620 Waukegan Road
McGaw Park IL 60085

Date Designated: 6/11/1992
Market Approval Date: Not currently Approved

Generic **Diazepam viscous solution for rectal administration**
Name:

Trade Name: NONE ASSIGNED

Designated *For the management of selected, refractory, patients with epilepsy, on stable regimens of antiepileptic drugs (AEDs), who require intermittent use of diazepam to control bouts of increased seizure activity.*
Indication:

Sponsor: Athena Neurosciences, Inc.
Address: 800f Gateway Boulevard
South San Francisco CA 94080

Date Designated: 2/25/1992
Market Approval Date: 7/29/1997

Generic **Diethyldithiocarbamate**
Name:

Trade **Imuthiol**
Name:

Designated *Treatment of AIDS.*
Indication:

Sponsor: **Connaught Laboratories**
Address: **Route 611, P.O. Box 187**
Swiftwater PA 18370

Date Designated: **4/3/1986**
Market Approval Date: **Not currently Approved**

Generic **digitoxin**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of soft tissue sarcomas*
Indication:

Sponsor: **PrimeCyte, Inc.**
Address: **130 Fifth Ave., N.**
Seattle WA 98109-4933

Date Designated: **10/18/2001**
Market Approval Date: **Not currently Approved**

Generic **digitoxin**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of ovarian cancer*
Indication:

Sponsor: **PrimeCyte, Inc.**
Address: **130 Fifth Ave., N.**
Seattle WA 98109-4933

Date Designated: **11/2/2001**
Market Approval Date: **Not currently Approved**

Generic **Digoxin immune FAB (Ovine)**
Name:

Trade **Digibind**
Name:

Designated *Treatment of potentially life threatening digitalis intoxication in patients who are refractory to management by*
Indication: *conventional therapy.*

Sponsor: **Glaxo Wellcome Inc.**
Address: **5 Moore Drive**
Research Triangle Park NC 27709

Date Designated: **11/1/1984**
Market Approval Date: **4/22/1986**

Generic **Digoxin immune fab(ovine)**
Name:

Trade **Digidote**
Name:

Designated *Treatment of life-threatening acute cardiac glycoside intoxication manifested by conduction disorders, ectopic*
Indication: *ventricular activity and (in some cases) hyperkalemia.*

Sponsor: **Boehringer Mannheim Corp.**
Address: **1301 Piccard Drive**
Rockville MD 20850

Date Designated: **3/11/1985**
Market Approval Date: **Not currently Approved**

Generic **Dihydrotestosterone** Trade Name: **Androgel -DHT**
Name:
Designated *Treatment of weight loss in AIDS patients with HIV-associated wasting.*
Indication:
Sponsor: **Unimed Pharmaceuticals, Inc.** Date Designated: **2/5/1996**
Address: **Four Parkway North** Market Approval Date: **Not currently Approved**
Deerfield IL 60015-2544

Generic **Dimethyl sulfoxide** Trade Name: **NONE ASSIGNED**
Name:
Designated *Treatment of increased intracranial pressure in patients with severe, closed-head injury, also known as traumatic*
Indication: *brain coma, for whom no other effective treatment is available.*
Sponsor: **Pharma 21** Date Designated: **11/22/1994**
Address: **c/o Univ. of Calif., San Diego** Market Approval Date: **Not currently Approved**
9500 Gilman Dr.
La Jolla CA 92093-0624

Generic **Dimethylsulfoxide** Trade Name: **NONE ASSIGNED**
Name:
Designated *Topical treatment for the prevention of soft tissue injury following extravasion of cytotoxic drugs.*
Indication:
Sponsor: **Cancer Technologies, Inc.** Date Designated: **4/15/1997**
Address: **7301 East 22nd Street** Market Approval Date: **Not currently Approved**
Suite 10E
Tucson AZ 85710

Generic **Dimethylsulfoxide** Trade Name: **NONE ASSIGNED**
Name:
Designated *Treatment of palmar-plantar erythrodysesthesia syndrome.*
Indication:
Sponsor: **Cancer Technologies, Inc.** Date Designated: **4/6/1998**
Address: **7301 East 22nd Street** Market Approval Date: **Not currently Approved**
Suite 10E
Tucson AZ 85710

Generic **Dipalmitoylphosphatidylcholine /phosphatidylglycerol** Trade Name: **ALEC**
Name:
Designated *Prevention and treatment of neonatal respiratory distress syndrome.*
Indication:
Sponsor: **Forum Products, Inc.** Date Designated: **7/28/1988**
Address: **33 Flying Point Road** Market Approval Date: **Not currently Approved**
Southampton NY 11968

Generic Name: **Disaccharide tripeptide glycerol dipalmitoyl** Trade Name: **Immther**
Designated Indication: *Treatment of pulmonary and hepatic metastases in patients with colorectal adenocarcinoma.*
Sponsor: **ImmunoTherapeutics, Inc.** Date Designated: **3/1/1990**
Address: **3505 Riverview Circle** Market Approval Date: **Not currently Approved**
Moorhead MN 56560

Generic Name: **Disodium clodronate** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of hypercalcemia of malignancy.*
Sponsor: **Discovery Experimental & Development, Inc.** Date Designated: **6/16/1993**
Address: **29949 S.R. 54 West** Market Approval Date: **Not currently Approved**
Wesley Chapel FL 33543

Generic Name: **Disodium clodronate tetrahydrate** Trade Name: **Bonefos**
Designated Indication: *Treatment of increased bone resorption due to malignancy.*
Sponsor: **Anthra Pharmaceuticals, Inc.** Date Designated: **3/5/1990**
Address: **103 Carnegie Center, Suite 102** Market Approval Date: **Not currently Approved**
Princeton NJ 08540

Generic Name: **DMP 777** Trade Name: **NONE ASSIGNED**
Designated Indication: *Therapeutic management of patients with lung disease attributable to cystic fibrosis.*
Sponsor: **DuPont Pharmaceuticals Company** Date Designated: **6/4/1996**
Address: **Chestnut Run, Maple Run** Market Approval Date: **Not currently Approved**
Centre Rd.
Wilmington DE 19805

Generic Name: **DNA-lipid complex (DMRIE/DOPE)/plasmid vector** Trade Name: **Leuvectin**
Designated Indication: *Treatment of renal cell carcinoma.*
Sponsor: **Vical Incorporated** Date Designated: **4/28/2000**
Address: **9373 Towne Center Dr.** Market Approval Date: **Not currently Approved**
Suite 100
San Diego CA 92121-3088

Generic **DNP-Modified autologous tumor vaccine**
Name:

Trade **O-Vax**
Name:

Designated *Adjuvant therapy for the treatment of ovarian cancer*
Indication:

Sponsor: AVAX Technologies, Inc.
Address: 9200 Indian Creek Parkway
Building 9, Suite 200
Overland Park KS 66210

Date Designated: 9/21/2000
Market Approval Date: Not currently Approved

Generic **docosahexanoic acid-paclitaxel**
Name:

Trade **Taxoprexin**
Name:

Designated *Treatment of hormone-refractory prostate cancer.*
Indication:

Sponsor: Protarga, Inc.
Address: 1100 East Hector Street
Suite 450
Conshohocken PA 19428-2377

Date Designated: 3/5/2001
Market Approval Date: Not currently Approved

Generic **Dornase alfa**
Name:

Trade **Pulmozyme**
Name:

Designated *To reduce mucous viscosity and enable the clearance of airway secretions in patients with cystic fibrosis.*
Indication:

Sponsor: Genentech, Inc.
Address: 460 Point San Bruno Boulevard
South San Francisco CA 94080

Date Designated: 1/16/1991
Market Approval Date: 12/30/1993

Generic **Doxorubicin liposome**
Name:

Trade **Doxil**
Name:

Designated *Treatment of ovarian cancer.*
Indication:

Sponsor: Alza Corporation
Address: 1550 Plymouth St.
PO Box 7210
Mountain View CA 94039-7210

Date Designated: 11/4/1998
Market Approval Date: 6/28/1999

Generic **Dronabinol**
Name:

Trade **Marinol**
Name:

Designated *For the stimulation of appetite and prevention of weight loss in patients with a confirmed diagnosis of AIDS.*
Indication:

Sponsor: Unimed Pharmaceuticals, Inc.
Address: 2150 East Lake Cook Road, Suite 210
Buffalo Grove IL 60089-1862

Date Designated: 1/15/1991
Market Approval Date: 12/22/1992

Generic **Duramycin** Trade Name: NONE ASSIGNED
Name:
Designated *Treatment of cystic fibrosis.*
Indication:
Sponsor: MoliChem Medicines Inc. Date Designated: 12/11/1997
Address: 207 South Elliott Road PMB#231 Market Approval Date: Not currently Approved
Chapel Hill NC 27514

Generic **Dynamine** Trade Name: NONE ASSIGNED
Name:
Designated *Treatment of Lambert Eaton myasthenic syndrome.*
Indication:
Sponsor: Mayo Foundation Date Designated: 2/5/1990
Address: 200 First Street Southwest Market Approval Date: Not currently Approved
Rochester MN 55905

Generic **Dynamine** Trade Name: NONE ASSIGNED
Name:
Designated *Treatment of hereditary motor and sensory neuropathy type I (Charcot-Marie-Tooth disease).*
Indication:
Sponsor: Mayo Foundation Date Designated: 10/16/1991
Address: 200 First Street Southwest Market Approval Date: Not currently Approved
Rochester MN 55905

Generic **Eflornithine HCl** Trade Name: Ornidyl
Name:
Designated *Treatment of Trypanosoma brucei gambiense infection (sleeping sickness).*
Indication:
Sponsor: Hoechst Marion Roussel Date Designated: 4/23/1986
Address: P.O. Box 9627 Market Approval Date: 11/28/1990
Kansas City MO 64134

Generic **Elcatonin** Trade Name: NONE ASSIGNED
Name:
Designated *Intrathecal treatment of intractable pain.*
Indication:
Sponsor: Innapharma, Inc. Date Designated: 9/25/1995
Address: 10 Mountainview Road Market Approval Date: Not currently Approved
Upper Saddle River NJ 07458

Generic Name: **Enadoline hydrochloride** Trade Name: NONE ASSIGNED
Designated Indication: *Treatment of severe head injury.*
Sponsor: Warner-Lambert Company Date Designated: 1/28/1997
Address: Parke-Davis Pharmaceutical Research Market Approval Date: Not currently Approved
2800 Plymouth Road
Ann Arbor MI 48105

Generic Name: **Encapsulated porcine islet preparation** Trade Name: BetaRx
Designated Indication: *Treatment of type I diabetic patients who are already on immunosuppression.*
Sponsor: VivoRx Date Designated: 7/5/1995
Address: 2825 Santa Monica Blvd. Market Approval Date: Not currently Approved
2nd Floor
Santa Monica CA 90404-2429

Generic Name: **Epidermal growth factor (human)** Trade Name: NONE ASSIGNED
Designated Indication: *For acceleration of corneal epithelial regeneration and the healing of stromal tissue in the condition of non-healing corneal defects.*
Sponsor: Chiron Vision Date Designated: 10/5/1987
Address: 500 Iolab Drive Market Approval Date: Not currently Approved
Claremont CA 91711

Generic Name: **Epirubicin** Trade Name: Ellence
Designated Indication: *Treatment of breast cancer.*
Sponsor: Pharmacia & Upjohn Company Date Designated: 9/14/1999
Address: 0634-298-113 Market Approval Date: 9/15/1999
7000 Portage Rd.
Kalamazoo MI 49001-0199

Generic Name: **Epoetin alfa** Trade Name: NONE ASSIGNED
Designated Indication: *Treatment of myelodysplastic syndrome.*
Sponsor: R. W. Johnson Pharmaceutical Research Date Designated: 12/20/1993
Address: Route 202, P.O. Box 300 Market Approval Date: Not currently Approved
Raritan NJ 08869-0602

Generic **Epoetin alfa**
Name:

Trade Name: **Epogen**

Designated Indication: *Treatment of anemia associated with HIV infection or HIV treatment.*

Sponsor: **Amgen, Inc.**
Address: **1840 Dehavilland Drive
Thousand Oaks CA 91320**

Date Designated: **7/1/1991**
Market Approval Date: **12/31/1990**

Generic **Epoetin alfa**
Name:

Trade Name: **Epogen**

Designated Indication: *Treatment of anemia associated with end stage renal disease.*

Sponsor: **Amgen, Inc.**
Address: **1840 Dehavilland Drive
Thousand Oaks CA 91320**

Date Designated: **4/10/1986**
Market Approval Date: **6/1/1989**

Generic **Epoetin alpha**
Name:

Trade Name: **Procrit**

Designated Indication: *Treatment of anemia of prematurity in preterm infants.*

Sponsor: **R. W. Johnson Pharmaceutical Research**
Address: **Route 202, P.O. Box 300
Raritan NJ 08869-0602**

Date Designated: **7/21/1988**
Market Approval Date: **Not currently Approved**

Generic **Epoetin alpha**
Name:

Trade Name: **Procrit**

Designated Indication: *Treatment of anemia associated with end stage renal disease.*

Sponsor: **R. W. Johnson Pharmaceutical Research**
Address: **Route 202 South
P.O. Box 300
Raritan NJ 08869**

Date Designated: **8/27/1987**
Market Approval Date: **Not currently Approved**

Generic **Epoetin alpha**
Name:

Trade Name: **Procrit**

Designated Indication: *Treatment of HIV associated anemia related to HIV infection or HIV treatment.*

Sponsor: **R. W. Johnson Pharmaceutical Research**
Address: **Route 202, P.O. Box 300
Raritan NJ 08869**

Date Designated: **3/7/1989**
Market Approval Date: **Not currently Approved**

Generic **Epoetin beta**
Name:

Trade Name: Marogen

Designated Indication: *Treatment of anemia associated with end stage renal disease.*

Sponsor: Chugai-USA, Inc.
Address: 3780 Hawthorn Court
Waukegan IL 60087

Date Designated: 10/22/1987
Market Approval Date: Not currently Approved

Generic **Epoprostenol**
Name:

Trade Name: Flolan

Designated Indication: *Treatment of secondary pulmonary hypertension due to intrinsic precapillary pulmonary vascular disease.*

Sponsor: GlaxoSmithKline
Address: Five Moore Dr.
PO Box 13398
Research Triangle Park NC 27709-3398

Date Designated: 3/22/1999
Market Approval Date: 4/14/2000

Generic **Epoprostenol**
Name:

Trade Name: Flolan

Designated Indication: *Treatment of primary pulmonary hypertension.*

Sponsor: Glaxo Wellcome Inc.
Address: 5 Moore Drive
Research Triangle Park NC 27709

Date Designated: 9/25/1985
Market Approval Date: 9/20/1995

Generic **Erwinia L-asparaginase**
Name:

Trade Name: Erwinase

Designated Indication: *Treatment of acute lymphocytic leukemia.*

Sponsor: Porton International, Inc.
Address: 7114 Springbrook Terrace, #200
Spotsylvania VA 22553

Date Designated: 7/30/1986
Market Approval Date: Not currently Approved

Generic **Erythropoietin (recombinant human)**
Name:

Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of anemia associated with end stage renal disease.*

Sponsor: McDonnell Douglas Corp
Address: P.O. Box 516, 107/2 MS10
St. Louis MO 63166

Date Designated: 8/19/1987
Market Approval Date: Not currently Approved

Generic **Etanercept**
Name:

Trade Name: **Enbrel**

Designated *Reduction in signs and symptoms of moderately to severely active polyarticular-course juvenile rheumatoid*
Indication: *arthritis in patients who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs.*

Sponsor: **Immunex Corporation**
Address: **51 University St.
Seattle WA 98101-2936**

Date Designated: **10/27/1998**
Market Approval Date: **5/27/1999**

Generic **Etanercept**
Name:

Trade Name: **Enbrel**

Designated *Treatment of Wegener's granulomatosis.*
Indication:

Sponsor: **Immunex Corporation**
Address: **51 University Street
Seattle WA 98101-2936**

Date Designated: **4/6/1999**
Market Approval Date: **Not currently Approved**

Generic **Ethanolamine oleate**
Name:

Trade Name: **Ethamolol**

Designated *Treatment of patients with esophageal varices that have recently bled, to prevent rebleeding.*
Indication:

Sponsor: **Block Drug Company, Inc.**
Address: **257 Cornelison Avenue
Jersey City NJ 07302**

Date Designated: **3/22/1984**
Market Approval Date: **12/22/1988**

Generic **Ethyl eicosapentaenoate**
Name:

Trade Name: **NONE ASSIGNED**

Designated *Treatment of Huntington's disease.*
Indication:

Sponsor: **Laxdale Ltd.**
Address: **Kings Park House, Laurelhill Business Park
Polmaise Road, Stirling FK7 9JQ
United Kingdom UK**

Date Designated: **4/6/2000**
Market Approval Date: **Not currently Approved**

Generic **Etidronate disodium**
Name:

Trade Name: **Didronel**

Designated *Treatment of hypercalcemia of malignancy inadequately managed by dietary modification and/or oral hydration.*
Indication:

Sponsor: **MGI Pharma, Inc.**
Address: **6300 West Old Shakopee Rd.
Suite 110
Bloomington MN 55438-2318**

Date Designated: **3/21/1986**
Market Approval Date: **4/21/1987**

Generic **Etiocholanedione**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of aplastic anemia.*
Indication:

Sponsor: SuperGen, Inc.
Address: Two Annabel Lane, Suite 220
Suite 10
San Ramon CA 94583

Date Designated: 11/3/1995
Market Approval Date: Not currently Approved

Generic **Etiocholanedione**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of Prader-Willi syndrome.*
Indication:

Sponsor: SuperGen, Inc.
Address: Two Annabel Lane, Suite 220
San Ramon CA 94583

Date Designated: 5/7/1996
Market Approval Date: Not currently Approved

Generic **Exemestane**
Name:

Trade **Aromasin**
Name:

Designated *Treatment of advanced breast cancer in postmenopausal women whose disease has progressed following tamoxifen*
Indication: *therapy.*

Sponsor: Pharmacia & Upjohn
Address: 7000 Portage Road
Mail Stop: 0636-298-113
Kalamazoo MI 49001-0199

Date Designated: 9/19/1991
Market Approval Date: 10/21/1999

Generic **Exisulind**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *For the suppression and control of colonic adenomatous polyps in the inherited disease adenomatous polyposis*
Indication: *coli.*

Sponsor: Cell Pathways, Inc.
Address: 702 Electronic Drive
Horsham PA 19044

Date Designated: 2/14/1994
Market Approval Date: Not currently Approved

Generic **Factor XIII concentrate (human) pasteurized**
Name:

Trade **Fibrogammin P**
Name:

Designated *Treatment of congenital factor XIII deficiency.*
Indication:

Sponsor: Aventis Behring L.L.C.
Address: 1020 First Ave.
PO Box 61501
King of Prussia PA 19406-0901

Date Designated: 1/16/1985
Market Approval Date: Not currently Approved

Generic **Fampridine** Trade Name: **Neurelan**
Name:
Designated *Treatment of chronic, incomplete spinal cord injury.*
Indication:
Sponsor: **Acorda Therapeutics, Inc.** Date Designated: **6/2/1997**
Address: **15 Skyline Dr.** Market Approval Date: **Not currently Approved**
Hawthorne NY 10532

Generic **Fampridine** Trade Name: **Neurelan**
Name:
Designated *Relief of symptoms of multiple sclerosis.*
Indication:
Sponsor: **Acorda Therapeutics** Date Designated: **6/2/1987**
Address: **15 Skyline Dr.** Market Approval Date: **Not currently Approved**
Hawthorne NY 10532

Generic **Felbamate** Trade Name: **Felbatol**
Name:
Designated *Treatment of Lennox-Gastaut syndrome.*
Indication:
Sponsor: **Wallace Laboratories** Date Designated: **1/24/1989**
Address: **301B College Road East** Market Approval Date: **7/29/1993**
Princeton NJ 08540

Generic **FIAU** Trade Name: **NONE ASSIGNED**
Name:
Designated *Adjunctive treatment of chronic active hepatitis B.*
Indication:
Sponsor: **Oclassen Pharmaceuticals, Inc.** Date Designated: **7/24/1992**
Address: **100 Pelican Way** Market Approval Date: **Not currently Approved**
San Rafael CA 94901

Generic **Fibrinogen (human)** Trade Name: **NONE ASSIGNED**
Name:
Designated *For the control of bleeding and prophylactic treatment of patients deficient in fibrinogen.*
Indication:
Sponsor: **Alpha Therapeutic Corporation** Date Designated: **8/23/1995**
Address: **5555 Valley Boulevard** Market Approval Date: **Not currently Approved**
Los Angeles CA 90032

Generic **Fibronectin (human plasma derived)**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of non-healing corneal ulcers or epithelial defects which have been unresponsive to conventional*
Indication: *therapy and the underlying cause has been eliminated.*

Sponsor: Melville Biologics, Inc.
Address: 310 East 67th Street
New York NY 10021

Date Designated: 9/5/1988
Market Approval Date: Not currently Approved

Generic **Filgrastim**
Name:

Trade **Neupogen**
Name:

Designated *Treatment of neutropenia associated with bone marrow transplants.*
Indication:

Sponsor: Amgen, Inc.
Address: 1840 Dehavilland Drive
Thousand Oaks CA 91320

Date Designated: 10/1/1990
Market Approval Date: 6/15/1994

Generic **Filgrastim**
Name:

Trade **Neupogen**
Name:

Designated *Reduction in the duration of neutropenia, fever, antibiotic use, and hospitalization, following induction and*
Indication: *consolidation treatment for acute myeloid leukemia.*

Sponsor: Amgen, Inc.
Address: One Amgen Center Dr.
Thousand Oaks CA 91320-1799

Date Designated: 11/7/1996
Market Approval Date: 4/2/1998

Generic **Filgrastim**
Name:

Trade **Neupogen**
Name:

Designated *Treatment of patients with AIDS who, in addition, are afflicted with cytomegalovirus retinitis and are being treated*
Indication: *with ganciclovir.*

Sponsor: Amgen, Inc.
Address: One Amgen Center Dr.
Thousand Oaks CA 91320-1799

Date Designated: 9/3/1991
Market Approval Date: Not currently Approved

Generic **Filgrastim**
Name:

Trade **Neupogen**
Name:

Designated *For use in the mobilization of peripheral blood progenitor cells for collection in patients who will receive*
Indication: *myeloablative or myelosuppressive chemotherapy.*

Sponsor: Amgen, Inc.
Address: 1840 Dehavilland Drive
Thousand Oaks CA 91320

Date Designated: 7/17/1995
Market Approval Date: 12/28/1995

Generic **Filgrastim**
Name:

Trade **Neupogen**
Name:

Designated *Treatment of patients with severe chronic neutropenia (absolute neutrophil count less than 500/mm3).*
Indication:

Sponsor: Amgen, Inc.
Address: 1840 Dehavilland Drive
Thousand Oaks CA 91320

Date Designated: 11/7/1990
Market Approval Date: 12/19/1994

Generic **Flucinolone**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment uveitis involving the posterior segment of the eye.*
Indication:

Sponsor: Bausch & Lomb Pharmaceuticals, Inc.
Address: 8500 Hidden River Parkway
Tampa FL 33637

Date Designated: 7/31/2000
Market Approval Date: Not currently Approved

Generic **Fludarabine phosphate**
Name:

Trade **Fludara**
Name:

Designated *Treatment of chronic lymphocytic leukemia (CLL), including refractory CLL.*
Indication:

Sponsor: Berlex Laboratories, Inc.
Address: 15049 San Pablo Avenue, P.O. Box 4099
Richmond CA 94804

Date Designated: 4/18/1989
Market Approval Date: 4/18/1991

Generic **Fludarabine phosphate**
Name:

Trade **Fludara**
Name:

Designated *Treatment and management of patients with non-Hodgkins lymphoma.*
Indication:

Sponsor: Berlex Laboratories, Inc.
Address: 15049 San Pablo Avenue
P.O. Box 4099
Richmond CA 94804-0099

Date Designated: 4/18/1989
Market Approval Date: Not currently Approved

Generic **Flunarizine**
Name:

Trade **Sibelium**
Name:

Designated *Treatment of alternating hemiplegia.*
Indication:

Sponsor: Janssen Research Foundation
Address: P.O. Box 200
Titusville NJ 08560

Date Designated: 1/6/1986
Market Approval Date: Not currently Approved

Generic **Fluorouracil** Trade **NONE ASSIGNED**
Name: Name:
Designated *For use in combination with interferon alpha-2a, recombinant, for the treatment of esophageal carcinoma.*
Indication:
Sponsor: Hoffmann-La Roche, Inc. Date Designated: 10/27/1989
Address: 340 Kingsland Street Market Approval Date: Not currently Approved
Nutley NJ 07110-1199

Generic **Fluorouracil** Trade **NONE ASSIGNED**
Name: Name:
Designated *For use in combination with interferon alpha-2a, recombinant, for the treatment of advanced colorectal carcinoma.*
Indication:
Sponsor: Hoffmann-La Roche, Inc. Date Designated: 4/18/1990
Address: 340 Kingsland Street Market Approval Date: Not currently Approved
Nutley NJ 07110-1199

Generic **Fluorouracil** Trade **Adrucil**
Name: Name:
Designated *For use in combination with leucovorin for therapy of metastatic adenocarcinoma of the colon and rectum.*
Indication:
Sponsor: Lederle Laboratories Date Designated: 2/6/1989
Address: Division of American Cyanamid Company Market Approval Date: Not currently Approved
401 N. Middletown Road
Pearl River NY 10965

Generic **Fluorouracil** Trade **NONE ASSIGNED**
Name: Name:
Designated *Treatment of glioblastoma multiforme.*
Indication:
Sponsor: Ethypharm SA Date Designated: 6/29/2000
Address: 194 Bureaux de la Colline - Batiment D Market Approval Date: Not currently Approved
92213 Saint-Cloud Cedex
France FR

Generic **Fluoxetine** Trade **Prozac**
Name: Name:
Designated *Treatment of autism.*
Indication:
Sponsor: Hollander, MD, Eric Date Designated: 4/30/1999
Address: Mt. Sinai School of Medicine, Dept. of Market Approval Date: Not currently Approved
Box 1230, One Gustave L. Levy Place
New York NY 10029-6574

Generic Name: **Follitropin alfa, recombinant**

Trade Name: **Gonal-F**

Designated Indication: *For the initiation and re-initiation of spermatogenesis in adult males with reproductive failure due to hypothalamic or pituitary dysfunction, hypogonadotropic hypogonadism. AMENDED indication 6/27/00: For the induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure.*

Sponsor: **Serono Laboratories, Inc.**
Address: **100 Longwater Circle
Norwell MA 02061**

Date Designated: **12/21/1998**
Market Approval Date: **5/24/2000**

Generic Name: **Fomepizole**

Trade Name: **Antizole**

Designated Indication: *Treatment of methanol or ethylene glycol poisoning.*

Sponsor: **Orphan Medical, Inc.**
Address: **13911 Ridgedale Drive
Suite 250
Minnetonka MN 55305**

Date Designated: **12/22/1988**
Market Approval Date: **12/4/1997**

Generic Name: **Fomepizole**

Trade Name: **Antizole**

Designated Indication: *Treatment of methanol or ethylene glycol poisoning.*

Sponsor: **Orphan Medical, Inc.**
Address: **13911 Ridgedale Drive
Suite 250
Minnetonka MN 55305**

Date Designated: **12/22/1988**
Market Approval Date: **12/8/2000**

Generic Name: **Fosphenytoin**

Trade Name: **Cerebyx**

Designated Indication: *For the acute treatment of patients with status epilepticus of the grand mal type.*

Sponsor: **Warner-Lambert Company**
Address: **2800 Plymouth Road
Ann Arbor MI 48106**

Date Designated: **6/4/1991**
Market Approval Date: **8/5/1996**

Generic Name: **Fructose-1,6-diphosphate**

Trade Name: **Cordox**

Designated Indication: *Treatment of painful vaso-occlusive episodes associated with sickle cell disease.*

Sponsor: **Questcor Pharmaceuticals, Inc.**
Address: **3260 Whipple Road
Union City CA 94587-1217**

Date Designated: **5/29/1998**
Market Approval Date: **Not currently Approved**

Generic Name: **Gabapentin** Trade Name: **Neurontin**
Designated Indication: *Treatment of amyotrophic lateral sclerosis.*
Sponsor: Warner-Lambert Company Date Designated: 7/5/1995
Address: Parke-Davis Pharmaceutical Research Market Approval Date: Not currently Approved
2800 Plymouth Road
Ann Arbor MI 48105

Generic Name: **Gallium nitrate injection** Trade Name: **Ganite**
Designated Indication: *Treatment of hypercalcemia of malignancy.*
Sponsor: Solopak Pharmaceutical Co. Date Designated: 12/5/1988
Address: 1845 Tonne Road Market Approval Date: 1/17/1991
Elk Grove Village IL 60007

Generic Name: **Gamma hydroxybutyrate** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of narcolepsy and the auxiliary symptoms of cataplexy, sleep paralysis, hypnagogic hallucinations and automatic behavior.*
Sponsor: Biocraft Laboratories, Inc. Date Designated: 12/3/1987
Address: 18-01 River Road Market Approval Date: Not currently Approved
Fair Lawn NJ 07410

Generic Name: **Gammalinolenic acid** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of juvenile rheumatoid arthritis.*
Sponsor: Zurier, Robert B. M.D. Date Designated: 7/27/1994
Address: University of Massachusetts Medical Center Market Approval Date: Not currently Approved
55 Lake Avenue
Worcester MA 01655

Generic Name: **Ganaxolone** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of infantile spasms.*
Sponsor: Purdue Pharma L.P. Date Designated: 5/25/1994
Address: 100 Connecticut Ave. Market Approval Date: Not currently Approved
Norwalk CT 06850-3590

Generic Name: **Ganciclovir intravitreal implant**

Trade Name: **Vitraser Implant**

Designated Indication: *Treatment of cytomegalovirus retinitis.*

Sponsor: **Bausch & Lomb Surgical, Chiron Vision**
Address: **9342 Jeronimo Road
Irvine CA 92718-1903**

Date Designated: **6/7/1995**
Market Approval Date: **3/4/1996**

Generic Name: **Ganciclovir sodium**

Trade Name: **Cytovene**

Designated Indication: *Treatment of cytomegalovirus retinitis in immunocompromised patients with AIDS.*

Sponsor: **Syntex (USA), Inc.**
Address: **3401 Hillview Avenue
Palo Alto CA 94304**

Date Designated: **10/31/1985**
Market Approval Date: **6/23/1989**

Generic Name: **Gavilimomab**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Acute graft-versus-host disease (aGVHD)*

Sponsor: **Abgenix, Inc.**
Address: **7601 Dumbarton Circle
Fremont CA 94555**

Date Designated: **11/20/2000**
Market Approval Date: **Not currently Approved**

Generic Name: **Gemtuzumab zogamicin**

Trade Name: **Mylotarg**

Designated Indication: *Treatment of CD33-positive acute myeloid leukemia.*

Sponsor: **Wyeth-Ayerst Laboratories**
Address: **PO Box 8299
Philadelphia PA 19101-8299**

Date Designated: **11/24/1999**
Market Approval Date: **5/17/2000**

Generic Name: **Gene plasmid hVEGF165 driven by human cytomegalovirus, and [2,3-bis(oleoyl)propyl]trimethyl ammonium and dioleoyl phosphatidyl ethanolamine**

Trade Name: **Trinam**

Designated Indication: *Prevention of complications due to neointimal hyperplasia disease in certain vascular anastomoses.*

Sponsor: **Ark Therapeutics Ltd.**
Address: **6 Warren Mews
London W1P 5DJ UK**

Date Designated: **10/24/2000**
Market Approval Date: **Not currently Approved**

Generic Name: **Gentamicin impregnated PMMA beads on surgical wire** Trade Name: **Septopal**
Designated Indication: *Treatment of chronic osteomyelitis of post-traumatic, postoperative, or hematogenous origin.*
Sponsor: **Lipha Pharmaceuticals, Inc.** Date Designated: **1/31/1991**
Address: **9 West 57th Street** Market Approval Date: **Not currently Approved**
Suite 3825
New York NY 10019-2701

Generic Name: **Gentamicin liposome injection** Trade Name: **Maitec**
Designated Indication: *Treatment of disseminated Mycobacterium avium-intracellulare infection.*
Sponsor: **Liposome Company, Inc.** Date Designated: **7/10/1990**
Address: **One Research Way** Market Approval Date: **Not currently Approved**
Princeton NJ 08540

Generic Name: **Glatiramer acetate** Trade Name: **Copaxone**
Designated Indication: *Treatment of multiple sclerosis.*
Sponsor: **Teva Pharmaceuticals USA** Date Designated: **11/9/1987**
Address: **1510 Delp Drive** Market Approval Date: **12/20/1996**
Kulpsville PA 19443

Generic Name: **Glatiramer acetate for injection** Trade Name: **Copaxone**
Designated Indication: *Treatment of primary-progressive multiple sclerosis*
Sponsor: **TEVA Pharmaceuticals, USA** Date Designated: **6/5/2001**
Address: **1090 Horsham Road** Market Approval Date: **Not currently Approved**
North Wales PA 19454

Generic Name: **Glutamine** Trade Name: **NONE ASSIGNED**
Designated Indication: *For use with human growth hormone in the treatment of short bowel syndrome (nutrient malabsorption from the gastrointestinal tract resulting from an inadequate absorptive surface).*
Sponsor: **Nutritional Restart Pharmaceutical, L.P.** Date Designated: **3/6/1995**
Address: **4364 South Alston Avenue** Market Approval Date: **Not currently Approved**
Durham NC 27713

Generic Name:	Glyceryl trioleate and glyceryl trierucate	Trade Name:	NONE ASSIGNED
Designated Indication:	<i>Treatment of adrenoleukodystrophy.</i>		
Sponsor:	Moser, Hugo W. M.D.	Date Designated:	2/14/1995
Address:	Johns Hopkins University Kennedy Krieger Institute, 707 North Baltimore MD 21205	Market Approval Date:	Not currently Approved

Generic Name:	Gonadorelin acetate	Trade Name:	Lutrepulse
Designated Indication:	<i>For induction of ovulation in women with hypothalamic amenorrhea due to a deficiency or absence in the quantity or pulse pattern of endogenous GnRH secretion.</i>		
Sponsor:	Ferring Laboratories, Inc.	Date Designated:	4/22/1987
Address:	400 Rella Boulevard, Suite 201 Suffern NY 10901	Market Approval Date:	10/10/1989

Generic Name:	Gossypol	Trade Name:	NONE ASSIGNED
Designated Indication:	<i>Treatment of cancer of the adrenal cortex.</i>		
Sponsor:	Reidenberg, Marcus M. M.D.	Date Designated:	10/22/1990
Address:	The New York Hospital - Cornell Medical 525 East 68th Street, Box 70 New York NY 10021	Market Approval Date:	Not currently Approved

Generic Name:	Gp100 adenoviral gene therapy	Trade Name:	NONE ASSIGNED
Designated Indication:	<i>Treatment of metastatic melanoma.</i>		
Sponsor:	Genzyme Corporation	Date Designated:	3/25/1997
Address:	One Mountain Rd. P.O. Box 9322 Framingham MA 01701-9322	Market Approval Date:	Not currently Approved

Generic Name:	Growth hormone releasing factor	Trade Name:	NONE ASSIGNED
Designated Indication:	<i>For the long-term treatment of children who have growth failure due to a lack of adequate endogenous growth hormone secretion.</i>		
Sponsor:	ICN Pharmaceuticals, Inc.	Date Designated:	8/7/1989
Address:	ICN Plaza 3300 Hyland Avenue Costa Mesa CA 92626	Market Approval Date:	Not currently Approved

Generic Name: **Guanfacine** Trade Name: **Tenex**
Designated Indication: *Treatment of fragile X syndrome.*
Sponsor: **Watson Laboratories, Inc.** Date Designated: **8/5/1999**
Address: **311 Bonnie Circle** Market Approval Date: **Not currently Approved**
PO Box 1900
Corona CA 91718-1900

Generic Name: **h5G1.1-mAb** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of dermatomyositis*
Sponsor: **Alexion Pharmaceuticals, Inc.** Date Designated: **9/21/2000**
Address: **352 Knotter Drive** Market Approval Date: **Not currently Approved**
Cheshire CT 06410

Generic Name: **h5G1.1mAb** Trade Name: **NONE ASSIGNED**
Designated Indication: *Idiopathic membranous glomerular nephropathy*
Sponsor: **Alexion Pharmaceuticals, Inc.** Date Designated: **3/5/2001**
Address: **352 Knotter Drive** Market Approval Date: **Not currently Approved**
Cheshire CT 06410

Generic Name: **Halofantrine** Trade Name: **Halfan**
Designated Indication: *Treatment of mild to moderate acute malaria caused by susceptible strains of P. falciparum and P. vivax.*
Sponsor: **SmithKline Beecham Pharmaceuticals** Date Designated: **11/4/1991**
Address: **One Franklin Plaza** Market Approval Date: **7/24/1992**
P.O. Box 7929
Philadelphia PA 19101

Generic Name: **Halofuginone** Trade Name: **Stenorol**
Designated Indication: *Treatment of systemic sclerosis.*
Sponsor: **Collgard Biopharmaceuticals Ltd.** Date Designated: **2/7/2000**
Address: **Textile House, 2 Koifman St.** Market Approval Date: **Not currently Approved**
Tel-Aviv 68012
Israel IL

Generic **Heme arginate**
Name:

Trade **Normosang**
Name:

Designated *Treatment of symptomatic stage of acute porphyria.*
Indication:

Sponsor: Berlex Laboratories, Inc.
Address: 15049 San Pablo Avenue
Richmond CA 94804-0099

Date Designated: 3/10/1988
Market Approval Date: Not currently Approved

Generic **Heme arginate**
Name:

Trade **Normosang**
Name:

Designated *Treatment of myelodysplastic syndromes.*
Indication:

Sponsor: Berlex Laboratories, Inc.
Address: 15049 San Pablo Avenue
Richmond CA 94804-0099

Date Designated: 3/1/1994
Market Approval Date: Not currently Approved

Generic **Hemin**
Name:

Trade **Panhematin**
Name:

Designated *Amelioration of recurrent attacks of acute intermittent porphyria (AIP) temporarily related to the menstrual cycle in susceptible women and similar symptoms which occur in other patients with AIP, porphyria variegata and hereditary coproporphyria.*
Indication:

Sponsor: Abbott Laboratories
Address: Diagnostics Division
Abbott Park IL 60064

Date Designated: 3/16/1984
Market Approval Date: 7/20/1983

Generic **Hemin and zinc mesoporphyrin**
Name:

Trade **Hemex**
Name:

Designated *Treatment of acute porphyric syndromes.*
Indication:

Sponsor: Bonkovsky, Herbert L. M.D.
Address: University Of Massachusetts Medical Center
55 Lake Avenue North
Worcester MA 01655

Date Designated: 12/20/1993
Market Approval Date: Not currently Approved

Generic **Hepatitis B immune globulin intravenous (human)**
Name:

Trade **Nabi-HB**
Name:

Designated *Prophylaxis against hepatitis B virus reinfection in liver transplant patients.*
Indication:

Sponsor: NABI
Address: 12280 Wilkins Avenue
Rockville MD 20852

Date Designated: 3/8/1995
Market Approval Date: Not currently Approved

Generic **Herpes simplex virus gene**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of primary and metastatic brain tumors.*
Indication:

Sponsor: Genetic Therapy, Inc.
Address: 938 Clopper Road
Gaithersburg MD 20878

Date Designated: 10/16/1992
Market Approval Date: Not currently Approved

Generic **Histamine**
Name:

Trade **Maxamine**
Name:

Designated *For use as an adjunct to cytokine therapy in the treatment of malignant melanoma.*
Indication:

Sponsor: Maxim Pharmaceuticals, Inc.
Address: 8899 University Center Lane
Suite 400
San Diego CA 92122

Date Designated: 2/1/2000
Market Approval Date: Not currently Approved

Generic **Histamine**
Name:

Trade **Maxamine**
Name:

Designated *Adjunct to cytokine therapy in the treatment of acute myeloid leukemia.*
Indication:

Sponsor: Maxim Pharmaceuticals, Inc.
Address: 8899 University Center Lane
Suite 400
San Diego CA 92122

Date Designated: 12/15/1999
Market Approval Date: Not currently Approved

Generic **Histrelin**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of acute intermittent porphyria, hereditary coproporphyria, and variegate porphyria.*
Indication:

Sponsor: Anderson, Karl E., M.D.
Address: University of Texas Medical Branch at
Route J-09, 700 The Strand
Galveston TX 77550

Date Designated: 5/3/1991
Market Approval Date: Not currently Approved

Generic **Histrelin acetate**
Name:

Trade **Supprelin Injection**
Name:

Designated *Treatment of central precocious puberty.*
Indication:

Sponsor: Roberts Pharmaceutical Corp.
Address: Meridian Center III
6 Industrial Way West
Eatontown NJ 07724

Date Designated: 8/10/1988
Market Approval Date: 12/24/1991

Generic Name: **HLA-B7/Beta2M DNA Lipid (DMRIE/DOPE) Complex** Trade Name: **Allovectin-7**
Designated Indication: *Treatment of invasive and metastatic melanoma (Stages II, III, and IV).*
Sponsor: **Vical Incorporated** Date Designated: **9/30/1999**
Address: **9373 Towne Centre Dr., Suite 100** Market Approval Date: **Not currently Approved**
San Diego CA 92121

Generic Name: **Hsp E7** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of recurrent respiratory papillomatosis (RRP)*
Sponsor: **StressGen Biotechnologies, Inc.** Date Designated: **3/19/2001**
Address: **409 2nd Avenue** Market Approval Date: **Not currently Approved**
Suite 201
Collegeville PA 19426-2655

Generic Name: **Hu1D10, humanized monoclonal antibody** Trade Name: **Remitogen**
Designated Indication: *For use in the treatment of 1D10+ B cell non-Hodgkin's lymphoma*
Sponsor: **Protein Design Labs, Inc.** Date Designated: **11/28/2001**
Address: **34801 Campus Drive** Market Approval Date: **Not currently Approved**
Fremont CA 94555

Generic Name: **Human acid precursor alpha-glucosidase, recombinant** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of glycogen storage disease type II.*
Sponsor: **Pharming/Genzyme LLC** Date Designated: **9/10/1996**
Address: **c/o Genzyme Corporation** Market Approval Date: **Not currently Approved**
1 Mountain Rd.
Framingham MA 01701-9322

Generic Name: **human gammaglobulin** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment for juvenile rheumatoid arthritis*
Sponsor: Protein Therapeutics, Inc. Date Designated: 5/25/2001
Address: 9040 S. Rita Rd., Suite 1100 Market Approval Date: Not currently Approved
Tucson AZ 84747

Generic Name: **Human T-lymphotropic virus type III Gp160 antigens** Trade Name: **Vaxsyn HIV-1**
Designated Indication: *Treatment of AIDS.*
Sponsor: MicroGeneSys, Inc. Date Designated: 11/20/1989
Address: 1000 Research Parkway Market Approval Date: Not currently Approved
Meriden CT 06450

Generic Name: **Humanized anti-CD2 monoclonal antibody** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of graft-versus-host disease.*
Sponsor: MedImmune, Inc. Date Designated: 11/13/1998
Address: 35 West Watkins Mill Rd. Market Approval Date: Not currently Approved
Gaithersburg MD 20878

Generic Name: **Humanized anti-human CD2 MAb** Trade Name: **MEDI-507**
Designated Indication: *For the induction of donor-specific immunologic unresponsiveness resulting in prophylaxis of organ rejection without the need for chronic immunosuppressive therapy, in patients receiving allogeneic renal transplants.*
Sponsor: Biotransplant, Inc. Date Designated: 9/17/1998
Address: Building 75, 3rd. Ave. Market Approval Date: Not currently Approved
Charlestown Navy Yard
Charlestown MA 02129

Generic Name: **Humanized anti-tac** Trade Name: **Zenapax**
Designated Indication: *Prevention of acute graft-vs-host disease following bone marrow transplantation.*
Sponsor: Hoffmann-La Roche, Inc. Date Designated: 3/5/1993
Address: 340 Kingsland Street Market Approval Date: Not currently Approved
Nutley NJ 07110-1199

Generic Name: **Humanized Mab (IDEC-131) to CD40L** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of systemic lupus erythematosus.*
Sponsor: **Idec Pharmaceuticals Corporation** Date Designated: **2/9/1999**
Address: **3030 Callan Rd.** Market Approval Date: **Not currently Approved**
San Diego CA 92121

Generic Name: **humanized monoclonal antibody against Shiga-like toxin II** Trade Name: **NONE ASSIGNED**
Designated Indication: *To prevent the development of or to decrease the incidence and severity of hemolytic uremic syndrome and associated sequelae of Shiga-like toxin-producing E. coli.*
Sponsor: **Teijin America, Inc.** Date Designated: **9/12/2001**
Address: **600 Alexander Park** Market Approval Date: **Not currently Approved**
Suite 304
Princeton NJ 08540

Generic Name: **Hydroxocobalamin** Trade Name: **CYANOKIT**
Designated Indication: *Treatment of acute cyanide poisoning*
Sponsor: **Orphan Medical, Inc.** Date Designated: **9/22/2000**
Address: **13911 Ridgedale Drive** Market Approval Date: **Not currently Approved**
Suite 250
Minnetonka MN 55305

Generic Name: **Hydroxyurea** Trade Name: **Droxia**
Designated Indication: *Treatment of patients with sickle cell anemia as shown by the presence of hemoglobin S.*
Sponsor: **Bristol-Myers Squibb Pharmaceutical** Date Designated: **10/1/1990**
Address: **P.O. Box 4000** Market Approval Date: **2/25/1998**
Princeton NJ 08543

Generic Name: **Hypericin** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of glioblastoma multiforme.*
Sponsor: **Nexell Therapeutics** Date Designated: **8/3/2000**
Address: **2751 Centerville Rd., Suite 210** Market Approval Date: **Not currently Approved**
Wilmington DE 19808

Generic Name: **Hypericin** Trade Name: NONE ASSIGNED
Designated Indication: *Treatment of cutaneous T-cell lymphoma.*
Sponsor: Nexell Therapeutics, Inc. Date Designated: 2/7/2000
Address: 2751 Centerville Rd., Suite 210 Market Approval Date: Not currently Approved
Wilmington DE 19808

Generic Name: **Ibuprofen i.v. solution** Trade Name: NONE ASSIGNED
Designated Indication: *Treatment of patent ductus arteriosus.*
Sponsor: Farmacon-IL-LLC Date Designated: 10/29/1996
Address: 1720 Post Road East Market Approval Date: Not currently Approved
Suite 213
Westport CT 06880-5643

Generic Name: **Ibuprofen i.v. solution** Trade Name: Salprofen
Designated Indication: *Prevention of patent ductus arteriosus.*
Sponsor: Farmacon-IL, LLC Date Designated: 10/29/1996
Address: 1720 Post Road East Market Approval Date: Not currently Approved
Suite 213
Westport CT 06880-5643

Generic Name: **Icodextrin 7.5% with Electrolytes Peritoneal Dialysis Solution** Trade Name: Extraneal (with 7.5% Icodextrin) Peritoneal Dialysis Solutio
Designated Indication: *Treatment of those patients having end stage renal disease and requiring peritoneal dialysis treatment.*
Sponsor: Baxter Healthcare Corporation Date Designated: 7/18/1997
Address: Renal Division Market Approval Date: Not currently Approved
1620 Waukegan Road
McGaw Park IL 60085

Generic Name: **Idarubicin HCl for injection** Trade Name: Idamycin
Designated Indication: *Treatment of acute myelogenous leukemia, also referred to as acute nonlymphocytic leukemia.*
Sponsor: Adria Laboratories, Inc. Date Designated: 7/25/1988
Address: P.O. Box 16529 Market Approval Date: 9/27/1990
Columbus OH 43216

Generic **Idarubicin HCl for injection**
Name:

Trade **Idamycin**
Name:

Designated *Treatment of acute lymphoblastic leukemia in pediatric patients.*
Indication:

Sponsor: Pharmacia & Upjohn
Address: 7000 Portage Road
Unit 0633-298-113
Kalamazoo MI 49001-0199

Date Designated: 2/12/1991
Market Approval Date: Not currently Approved

Generic **Idoxuridine**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of nonparenchymatous sarcomas.*
Indication:

Sponsor: NeoPharm, Inc.
Address: 225 East Deerpath, Suite 250
Lake Forest IL 60045

Date Designated: 4/8/1996
Market Approval Date: Not currently Approved

Generic **iduronate-2-sulfatase**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Long term enzyme replacement therapy for patients with MPS II (Hunter Syndrome)*
Indication:

Sponsor: Transkaryotic Therapies Inc.
Address: 195 Albany Street
Cambridge MA 02139

Date Designated: 11/28/2001
Market Approval Date: Not currently Approved

Generic **Ifosfamide**
Name:

Trade **Ifex**
Name:

Designated *Treatment of testicular cancer.*
Indication:

Sponsor: Bristol-Myers Squibb Pharmaceutical
Address: 5 Research Parkway, P.O. Box 5100
Wallingford CT 06492

Date Designated: 1/20/1987
Market Approval Date: 12/30/1988

Generic **Ifosfamide**
Name:

Trade **Ifex**
Name:

Designated *Treatment of soft tissue sarcomas.*
Indication:

Sponsor: Bristol-Myers Squibb Pharmaceutical
Address: P.O. Box 4000
Princeton NJ 08543

Date Designated: 8/7/1985
Market Approval Date: Not currently Approved

Generic **Ifosfamide**
Name:

Trade Name: Ifex

Designated *Treatment of bone sarcomas.*
Indication:

Sponsor: Bristol-Myers Squibb Pharmaceutical
Address: P.O. Box 4000
Princeton NJ 08543-4000

Date Designated: 8/7/1985
Market Approval Date: Not currently Approved

Generic **IL-4 Pseudomonas Toxin Fusion Protein**
Name: **(IL-4(38-37)-PE38KDEL)**

Trade Name: NONE ASSIGNED

Designated *Treatment of astrocytic glioma.*
Indication:

Sponsor: Neurocrine Biosciences, Inc.
Address: 10555 Science Center Dr.
San Diego CA 92121

Date Designated: 4/6/2000
Market Approval Date: Not currently Approved

Generic **IL13-PE38QQR**
Name:

Trade Name: NONE ASSIGNED

Designated *Treatment of malignant glioma*
Indication:

Sponsor: NeoPharm, Inc.
Address: 150 Field Drive
Suite 195
Lake Forest IL 60045

Date Designated: 11/2/2001
Market Approval Date: Not currently Approved

Generic **Imatinib**
Name:

Trade Name: Gleevec

Designated *Treatment of chronic myelogenous leukemia*
Indication:

Sponsor: Novartis Pharmaceuticals Corporation
Address: 59 Route 10
East Hanover NJ 07936-1080

Date Designated: 1/31/2001
Market Approval Date: 5/10/2001

Generic **imatinib mesylate**
Name:

Trade Name: Gleevec

Designated *Treatment of gastrointestinal stromal tumors*
Indication:

Sponsor: Novartis Pharmaceuticals Corp.
Address: One Health Plaza
East Hanover NJ 07936-1080

Date Designated: 11/1/2001
Market Approval Date: Not currently Approved

Generic Name: **Imciromab pentetate** Trade Name: **Myoscint**
Designated Indication: *Detecting early necrosis as an indication of rejection of orthotopic cardiac transplants.*
Sponsor: Centocor, Inc. Date Designated: 1/25/1989
Address: 244 Great Valley Parkway Market Approval Date: Not currently Approved
Malvern PA 19355

Generic Name: **Imexon** Trade Name: **n/a**
Designated Indication: *Treatment of metastatic malignant melanoma*
Sponsor: AmpliMed Corporation Date Designated: 8/3/2001
Address: 2321 Camino La Zorrela Market Approval Date: Not currently Approved
Tucson AZ 85718

Generic Name: **Imexon** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of multiple myeloma.*
Sponsor: AmpliMed Corporation Date Designated: 11/8/1996
Address: 2321 Camino La Zorrela Market Approval Date: Not currently Approved
Tucson AZ 85718

Generic Name: **Imiglucerase** Trade Name: **Cerezyme**
Designated Indication: *Replacement therapy in patients with types I, II, and III Gaucher's disease.*
Sponsor: Genzyme Corporation Date Designated: 11/5/1991
Address: One Kendall Square Market Approval Date: 5/23/1994
Cambridge MA 02139-1562

Generic Name: **Immune globulin intravenous, human** Trade Name: **Gamimmune N**
Designated Indication: *Infection prophylaxis in pediatric patients affected with the human immunodeficiency virus.*
Sponsor: Bayer Corporation Date Designated: 2/18/1993
Address: Pharmaceutical Division, Biological Products Market Approval Date: 12/27/1993
400 Morgan Lane
New Haven CT 06516

Generic Name: **Imported fire ant venom, allergenic extract** Trade Name: **NONE ASSIGNED**
Designated Indication: *For skin testing of victims of fire ant stings to confirm fire ant sensitivity and if positive, for use as immunotherapy for the prevention of IgE-mediated anaphylactic reactions.*
Sponsor: **ALK Laboratories, Inc.** Date Designated: **5/12/1992**
Address: **Research Center** Market Approval Date: **Not currently Approved**
27 Village Lane
Wallingford CT 06492

Generic Name: **Indium In 111 murine monoclonal antibody FAB to myosin** Trade Name: **Myoscint**
Designated Indication: *To aid in the diagnosis of myocarditis.*
Sponsor: **Centocor, Inc.** Date Designated: **8/7/1989**
Address: **244 Great Valley Parkway** Market Approval Date: **Not currently Approved**
Malvern PA 19355

Generic Name: **Indium-In-111 murine MAb(2B8-MX-DTPA) & Yttrium-Y90 murine MAb(2B8-MX-DTPA)** Trade Name: **Melimmune**
Designated Indication: *Treatment of B-cell non-Hodgkin's lymphoma.*
Sponsor: **IDEC Pharmaceuticals Corporation** Date Designated: **9/6/1994**
Address: **3030 Callan Road** Market Approval Date: **Not currently Approved**
San Diego CA 92121

Generic Name: **Infliximab** Trade Name: **Remicade**
Designated Indication: *Treatment of moderately to severely active Crohn's disease for the reduction of the signs and symptoms, in patients who have an inadequate response to conventional therapy; and treatment of patients with fistulizing Crohn's disease for the reduction in the number of draining enterocutaneous fistula(s).*
Sponsor: **Centocor, Inc.** Date Designated: **11/14/1995**
Address: **200 Great Valley Parkway** Market Approval Date: **8/24/1998**
Malvern PA 19355-1307

Generic Name: **INH-A00021** Trade Name: **NONE ASSIGNED**
Designated Indication: *Reduction (prevention) of nosocomial bacteremia caused by staphylococci in very low birth weight infants.*
Sponsor: **Inhibitex, Inc.** Date Designated: **6/13/2001**
Address: **8995 Westside Parkway** Market Approval Date: **Not currently Approved**
Suite 150
Alpharetta GA 30004

Generic Name: **Inosine pranobex**

Trade Name: **Isoprinosine**

Designated Indication: *Treatment of subacute sclerosing panencephalitis.*

Sponsor: **Newport Pharmaceuticals**
Address: **897 West Sixteenth Street**
Newport Beach CA 92663

Date Designated: **9/20/1988**
Market Approval Date: **Not currently Approved**

Generic Name: **Interferon alfa-2a**

Trade Name: **Roferon A**

Designated Indication: *Treatment of chronic myelogenous leukemia.*

Sponsor: **Hoffmann-La Roche, Inc.**
Address: **340 Kingsland Street**
Nutley NJ 07110

Date Designated: **6/6/1989**
Market Approval Date: **10/19/1995**

Generic Name: **Interferon alfa-2a (recombinant)**

Trade Name: **Roferon-A**

Designated Indication: *Treatment of AIDS related Kaposi's sarcoma.*

Sponsor: **Hoffmann-La Roche, Inc.**
Address: **340 Kingsland Street**
Nutley NJ 07110

Date Designated: **12/14/1987**
Market Approval Date: **11/21/1988**

Generic Name: **Interferon alfa-2a (recombinant)**

Trade Name: **Roferon-A**

Designated Indication: *Treatment of renal cell carcinoma.*

Sponsor: **Hoffmann-La Roche, Inc.**
Address: **340 Kingsland Street**
Nutley NJ 07110-1199

Date Designated: **4/18/1988**
Market Approval Date: **Not currently Approved**

Generic Name: **Interferon alfa-2a (recombinant)**

Trade Name: **Roferon-A**

Designated Indication: *For use in combination with fluorouracil for the treatment of esophageal carcinoma.*

Sponsor: **Hoffmann-La Roche, Inc.**
Address: **340 Kingsland Street**
Nutley NJ 07110-1199

Date Designated: **10/27/1989**
Market Approval Date: **Not currently Approved**

Generic **Interferon alfa-2a (recombinant)**
Name:

Trade Name: Roferon-A

Designated Indication: *For the concomitant administration with fluorouracil for the treatment of advanced colorectal cancer.*

Sponsor: Hoffmann-La Roche, Inc.
Address: 340 Kingsland Street
Nutley NJ 07110-1199

Date Designated: 5/14/1990
Market Approval Date: Not currently Approved

Generic **Interferon alfa-2a (recombinant)**
Name:

Trade Name: Roferon-A

Designated Indication: *For the treatment of metastatic malignant melanoma in combination with Teceleukin.*

Sponsor: Hoffmann-La Roche, Inc.
Address: 340 Kingsland Street
Nutley NJ 07110

Date Designated: 5/11/1990
Market Approval Date: Not currently Approved

Generic **Interferon alfa-2a (recombinant)**
Name:

Trade Name: Roferon-A

Designated Indication: *For the concomitant administration with Teceleukin for the treatment of metastatic renal cell carcinoma.*

Sponsor: Hoffmann-La Roche, Inc.
Address: 340 Kingsland Street
Nutley NJ 07119

Date Designated: 5/2/1990
Market Approval Date: Not currently Approved

Generic **Interferon alfa-2b (recombinant)**
Name:

Trade Name: Intron A

Designated Indication: *Treatment of AIDS-related Kaposi's sarcoma.*

Sponsor: Schering Corporation
Address: 2000 Galloping Hill Road
Kenilworth NJ 07033

Date Designated: 6/24/1987
Market Approval Date: 11/21/1988

Generic **Interferon beta (recombinant human)**
Name:

Trade Name: Avonex

Designated Indication: *Treatment of primary brain tumors.*

Sponsor: Biogen, Inc.
Address: 14 Cambridge Center
Cambridge MA 02142

Date Designated: 1/13/1993
Market Approval Date: Not currently Approved

Generic Name: **Interferon beta-1a** Trade Name: **Avonex**
Designated Indication: *Treatment of multiple sclerosis.*
Sponsor: Biogen, Inc. Date Designated: 12/16/1991
Address: 14 Cambridge Center Market Approval Date: 5/17/1996
Cambridge MA 02142

Generic Name: **Interferon Beta-1a** Trade Name: **Avonex**
Designated Indication: *Treatment of juvenile rheumatoid arthritis.*
Sponsor: Biogen, Inc. Date Designated: 10/14/1998
Address: 14 Cambridge Center Market Approval Date: Not currently Approved
Cambridge MA 02142

Generic Name: **Interferon beta-1a** Trade Name: **Rebif**
Designated Indication: *Treatment of patients with secondary progressive multiple sclerosis.*
Sponsor: Serono Laboratories, Inc. Date Designated: 3/11/1996
Address: 100 Longwater Circle Market Approval Date: Not currently Approved
Norwell MA 02061

Generic Name: **Interferon beta-1a (recombinant human)** Trade Name: **Avonex**
Designated Indication: *Treatment of pulmonary fibrosis.*
Sponsor: Biogen, Inc. Date Designated: 1/7/1999
Address: 14 Cambridge Center Market Approval Date: Not currently Approved
Cambridge MA 02142

Generic Name: **Interferon beta-1a (recombinant human)** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of acute non-A, non-B hepatitis.*
Sponsor: Biogen, Inc. Date Designated: 7/24/1992
Address: 14 Cambridge Center Market Approval Date: Not currently Approved
Cambridge MA 02142

Generic Name: **Interferon beta-1a (recombinant)** Trade Name: **Rebif**
Designated Indication: *Treatment of symptomatic patients with AIDS including all patients with CD4 T-cell counts less than 200 cells per mm3.*
Sponsor: **Serono Laboratories, Inc.** Date Designated: **12/2/1992**
Address: **100 Longwater Circle** Market Approval Date: **Not currently Approved**
Norwell MA 02061

Generic Name: **Interferon beta-1b** Trade Name: **Betaseron**
Designated Indication: *Treatment of multiple sclerosis.*
Sponsor: **Chiron Corp. & Berlex Laboratories** Date Designated: **11/17/1988**
Address: **4560 Horton Street** Market Approval Date: **7/23/1993**
Emeryville CA 94608

Generic Name: **Interferon gamma 1-b** Trade Name: **Actimmune**
Designated Indication: *Treatment of chronic granulomatous disease.*
Sponsor: **Genentech, Inc.** Date Designated: **9/30/1988**
Address: **460 Point San Bruno Boulevard** Market Approval Date: **12/20/1990**
South San Francisco CA 94080

Generic Name: **Interferon gamma-1b** Trade Name: **Actimmune**
Designated Indication: *Delaying time to disease progression in patients with severe, malignant osteopetrosis.*
Sponsor: **InterMune, Inc.** Date Designated: **9/30/1996**
Address: **3280 Bayshore Boulevard** Market Approval Date: **2/10/2000**
Brisbane CA 94005

Generic Name: **Interferon gamma-1b** Trade Name: **Actimmune**
Designated Indication: *Treatment of renal cell carcinoma.*
Sponsor: **Genentech, Inc.** Date Designated: **12/4/1995**
Address: **1 DNA Way** Market Approval Date: **Not currently Approved**
South San Francisco CA 94080-4990

Generic Name: **Interferon-alfa-1b** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of multiple myeloma*
Sponsor: Ernest C. Borden Date Designated: 4/17/2001
Address: Center for Cancer Drug Discovery and Market Approval Date: Not currently Approved
9500 Euclid Avenue
Cleveland OH 44195

Generic Name: **Interleukin-1 receptor antagonist, human recombinant** Trade Name: **Antril**
Designated Indication: *Treatment of juvenile rheumatoid arthritis.*
Sponsor: Amgen, Inc. Date Designated: 9/23/1991
Address: One Amgen Center Drive Market Approval Date: Not currently Approved
Thousand Oaks CA 91320-1799

Generic Name: **Interleukin-1 receptor antagonist, human recombinant** Trade Name: **Antril**
Designated Indication: *Prevention and treatment of graft versus host disease in transplant recipients.*
Sponsor: Amgen, Inc. Date Designated: 10/16/1992
Address: One Amgen Center Drive Market Approval Date: Not currently Approved
Thousand Oaks CA 91320-1799

Generic Name: **Interleukin-2** Trade Name: **Teleleukin**
Designated Indication: *Treatment of metastatic malignant melanoma.*
Sponsor: Hoffmann-La Roche, Inc. Date Designated: 2/6/1990
Address: 340 Kingsland Street Market Approval Date: Not currently Approved
Nutley NJ 07110

Generic Name: **Interleukin-2** Trade Name: **Tecleukin**
Designated Indication: *In combination with interferon alfa-2a for the treatment of metastatic renal cell carcinoma.*
Sponsor: Hoffmann-La Roche, Inc. Date Designated: 5/3/1990
Address: 340 Kingsland Street Market Approval Date: Not currently Approved
Nutley NJ 07110

Generic Name: **Interleukin-2** Trade Name: **Tecceleukin**
Designated Indication: *Treatment of metastatic renal cell carcinoma.*
Sponsor: Hoffmann-La Roche, Inc. Date Designated: 2/5/1990
Address: 340 Kingsland Street Market Approval Date: Not currently Approved
Nutley NJ 07110

Generic Name: **Interleukin-2** Trade Name: **Tecceleukin**
Designated Indication: *In combination with interferon alfa-2a for the treatment of metastatic malignant melanoma.*
Sponsor: Hoffmann-La Roche, Inc. Date Designated: 5/11/1990
Address: 340 Kingsland Street Market Approval Date: Not currently Approved
Nutley NJ 07110

Generic Name: **Intraoral fluoride releasing system** Trade Name: **IFRS**
Designated Indication: *Prevention of dental caries due to radiation-induced xerostomia in patients with head and neck cancer*
Sponsor: Digestive Care, Inc. Date Designated: 7/31/2001
Address: 1120 Win Drive Market Approval Date: Not currently Approved
Bethlehem PA 18017

Generic Name: **Iobenguane Sulfate I 131** Trade Name: **NONE ASSIGNED**
Designated Indication: *For use as a diagnostic adjunct in patients with pheochromocytoma.*
Sponsor: University of Michigan Date Designated: 11/14/1984
Address: UH B1 H410/0028 Market Approval Date: 3/21/1990
1500 E. Medical Center Drive
Ann Arbor MI 48109-0028

Generic Name: **Iodine 131 6B-iodomethyl-19-norcholesterol** Trade Name: **NONE ASSIGNED**
Designated Indication: *For use in adrenal cortical imaging.*
Sponsor: David E. Kuhl, M.D. Date Designated: 8/1/1984
Address: University of Michigan Medical Center/1500 Market Approval Date: Not currently Approved
B1G412 /0028 University Hospital
Ann Arbor MI 48109-0028

Generic Name: **Iodine I 123 murine monoclonal antibody to alpha-fetoprotein** Trade Name: **NONE ASSIGNED**
Designated Indication: *Detection of hepatocellular carcinoma and hepatoblastoma.*
Sponsor: Immunomedics, Inc. Date Designated: 9/30/1988
Address: 300 American Road Market Approval Date: Not currently Approved
Morris Plains NJ 07950

Generic Name: **Iodine I 123 murine monoclonal antibody to alpha-fetoprotein** Trade Name: **NONE ASSIGNED**
Designated Indication: *Detection of alpha-fetoprotein producing germ cell tumors.*
Sponsor: Immunomedics, Inc. Date Designated: 9/30/1988
Address: 300 American Road Market Approval Date: Not currently Approved
Morris Plains NJ 07950

Generic Name: **Iodine I 123 murine monoclonal antibody to hCG** Trade Name: **NONE ASSIGNED**
Designated Indication: *Detection of hCG producing tumors such as germ cell and trophoblastic cell tumors.*
Sponsor: Immunomedics, Inc. Date Designated: 11/7/1988
Address: 300 American Road Market Approval Date: Not currently Approved
Morris Plains NJ 07950

Generic Name: **Iodine I 131 bis(indium-diethylenetriaminepentaacetic acid)tyrosyllysine/hMN-14 x m734 F(ab')₂ bispecific monoclonal antibody** Trade Name: **Pentacea**
Designated Indication: *Treatment of small-cell lung cancer.*
Sponsor: IBC Pharmaceuticals, L.L.C. Date Designated: 2/22/2000
Address: 300 American Rd. Market Approval Date: Not currently Approved
Morris Plains NJ 07950

Generic Name: **Iodine I 131 murine monoclonal antibody IgG2a to B cell** Trade Name: **Immurait, LI-2-I-131**
Designated Indication: *Treatment of B-cell leukemia and B-cell lymphoma.*
Sponsor: Immunomedics, Inc. Date Designated: 9/18/1989
Address: 300 American Road Market Approval Date: Not currently Approved
Morris Plains NJ 07950

Generic Name: **Iodine I 131 murine monoclonal antibody to alpha-fetoprotein** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of hepatocellular carcinoma and hepatoblastoma.*
Sponsor: Immunomedics, Inc. Date Designated: 9/30/1988
Address: 300 American Road Market Approval Date: Not currently Approved
Morris Plains NJ 07950

Generic Name: **Iodine I 131 murine monoclonal antibody to alpha-fetoprotein** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of alpha-fetoprotein producing germ cell tumors.*
Sponsor: Immunomedics, Inc. Date Designated: 9/30/1988
Address: 300 American Road Market Approval Date: Not currently Approved
Morris Plains NJ 07950

Generic Name: **Iodine I 131 murine monoclonal antibody to hCG** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of hCG producing tumors such as germ cell and trophoblastic cell tumors.*
Sponsor: Immunomedics, Inc. Date Designated: 11/7/1988
Address: 300 American Road Market Approval Date: Not currently Approved
Morris Plains NJ 07950

Generic Name: **Iodine I-131 radiolabeled chimeric MAb tumor necrosis treatment (TNT-1B)** Trade Name: **131IChTNT-1**
Designated Indication: *Treatment of glioblastoma multiforme and anaplastic astrocytoma.*
Sponsor: Peregrine Pharmaceuticals, Inc. Date Designated: 2/12/1999
Address: 14282 Franklin Ave. Market Approval Date: Not currently Approved
Tustin CA 92780-7017

Generic Name: **Isobutyramide** Trade Name: **Isobutyramide oral solution**
Designated Indication: *Treatment of beta-hemoglobinopathies and beta-thalassemia syndromes.*
Sponsor: Perrine, Susan P., M.D. Date Designated: 12/18/1992
Address: Boston University Market Approval Date: Not currently Approved
Cancer Research Center
Boston MA 02118

Generic Name: **Isobutyramide** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of sickle cell disease and beta thalassemia.*
Sponsor: Alpha Therapeutic Corporation Date Designated: 5/25/1994
Address: 5555 Valley Boulevard Market Approval Date: Not currently Approved
Los Angeles CA 90032

Generic Name: **Japanese encephalitis vaccine (live, attenuated)** Trade Name: **NONE ASSIGNED**
Designated Indication: *Prevention of Japanese encephalitis.*
Sponsor: Boran Pharmaceuticals Date Designated: 5/19/1999
Address: 3F, Koryo Academytel, 437-3 Market Approval Date: Not currently Approved
Ahyun-Dong, Mapo-Gu, Seoul 121-010
South Korea KR

Generic Name: **L-2-oxothiazolidine-4-carboxylic acid** Trade Name: **Procysteine**
Designated Indication: *Treatment of amyotrophic lateral sclerosis.*
Sponsor: Transcend Therapeutics, Inc. Date Designated: 7/30/1996
Address: 640 Memorial Drive, 3rd Floor West Market Approval Date: Not currently Approved
Cambridge MA 02139

Generic Name: **L-2-oxothiazolidine-4-carboxylic acid** Trade Name: **Procysteine**
Designated Indication: *Treatment of adult respiratory distress syndrome.*
Sponsor: Transcend Therapeutics, Inc. Date Designated: 6/14/1994
Address: 640 Memorial Drive, 3rd Floor West Market Approval Date: Not currently Approved
Cambridge MA 02139

Generic Name: **L-5-hydroxytryptophan** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of tetrahydrobiopterin deficiency.*
Sponsor: Watson Laboratories, Inc. Date Designated: 1/20/1999
Address: 311 Bonnie Circle Market Approval Date: Not currently Approved
P.O. Box 1900
Corona CA 91718-1900

Generic Name: **L-baclofen** Trade Name: **Neuralgon**
Designated Indication: *Treatment of intractable spasticity associated with spinal cord injury or multiple sclerosis.*
Sponsor: Pharmascience Inc. Date Designated: 12/17/1991
Address: 6111 Royalmount, Suite 100 Market Approval Date: Not currently Approved
Montreal, Quebec H4P 2T4
Canada CA

Generic Name: **L-baclofen** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of trigeminal neuralgia.*
Sponsor: Fromm, Gerhard M.D. Date Designated: 7/13/1990
Address: University Of Pittsburgh School of Medicine Market Approval Date: Not currently Approved
Pittsburgh PA 15261

Generic Name: **L-baclofen** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of trigeminal neuralgia.*
Sponsor: Pharmascience Inc. Date Designated: 1/6/1998
Address: 6111 Royalmount, #100 Market Approval Date: Not currently Approved
Montreal, Quebec
Canada H4P 2T4 CA

Generic Name: **L-baclofen** Trade Name: **Neuralgon**
Designated Indication: *Treatment of intractable spasticity in children with cerebral palsy.*
Sponsor: Pharmascience Inc. Date Designated: 1/30/1992
Address: 6111 Royalmount, Suite 100 Market Approval Date: Not currently Approved
Montreal, Quebec H4P 2T4
Canada CA

Generic Name: **L-cycloserine** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of Gaucher's disease.*
Sponsor: Lev, Meir M.D. Date Designated: 8/1/1989
Address: The City College, City University Of NY Market Approval Date: Not currently Approved
Convent Avenue at 138 Street
New York NY 10031

Generic Name: **L-cysteine**

Trade Name: **NONE ASSIGNED**

Designated Indication: *For the prevention and lessening of photosensitivity in erythropoietic protoporphyria.*

Sponsor: **Orphan Pharmaceuticals, U.S.A., Inc.**
Address: **1101 Kermit Dr.
Suite 608
Nashville TN 37217**

Date Designated: **5/16/1994**
Market Approval Date: **Not currently Approved**

Generic Name: **L-glutamine**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of sickle cell disease*

Sponsor: **Orphan Drugs International, LLC (d.b.a. Hope)**
Address: **PO Box 0401
Montrose CA 91021-0401**

Date Designated: **8/1/2001**
Market Approval Date: **Not currently Approved**

Generic Name: **L-glutamyl-L-tryptophan**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of AIDS-related Kaposi's sarcoma.*

Sponsor: **Cytran Incorporated**
Address: **10230 N.E. Points Dr.
Suite 530
Kirkland WA 98033-7869**

Date Designated: **10/20/1999**
Market Approval Date: **Not currently Approved**

Generic Name: **L-leucovorin**

Trade Name: **Isovorin**

Designated Indication: *For use in combination chemotherapy with the approved agent 5-fluorouracil in the palliative treatment of metastatic adenocarcinoma of the colon and rectum.*

Sponsor: **Lederle Laboratories**
Address: **Division of American Cyanamid Company
401 N. Middletown Road
Pearl River NY 10965**

Date Designated: **12/18/1990**
Market Approval Date: **Not currently Approved**

Generic Name: **L-leucovorin**

Trade Name: **Isovorin**

Designated Indication: *For use in conjunction with high-dose methotrexate in the treatment of osteosarcoma.*

Sponsor: **Lederle Laboratories**
Address: **Division of American Cyanamid Company
401 N. Middletown Road
Pearl River NY 10965**

Date Designated: **8/1/1991**
Market Approval Date: **Not currently Approved**

Generic Name: **L-threonine**

Trade Name: **Threostat**

Designated Indication: *Treatment of amyotrophic lateral sclerosis.*

Sponsor: **Tyson And Associates**
Address: **12832 Chadron Avenue**
Hawthorne CA 90250

Date Designated: **2/6/1989**
Market Approval Date: **Not currently Approved**

Generic Name: **Lactic acid**

Trade Name: **Aphthaid**

Designated Indication: *Treatment of severe aphthous stomatitis in severely, terminally immunocompromised patients.*

Sponsor: **Frontier Pharmaceutical, Inc.**
Address: **SUNY Farmingdale**
Conklin Hall
Farmingdale NY 11735

Date Designated: **6/29/1999**
Market Approval Date: **Not currently Approved**

Generic Name: **Lamotrigine**

Trade Name: **Lamictal**

Designated Indication: *Treatment of Lennox-Gastaut syndrome.*

Sponsor: **Glaxo Wellcome Research and Development**
Address: **5 Moore Drive**
P.O. Box 13398
Research Triangle Park NC 27709

Date Designated: **8/23/1995**
Market Approval Date: **8/24/1998**

Generic Name: **Lanreotide, Somatostatin** Trade Name: **Ipstyl**
Designated Indication: *Treatment for acromegly*
Sponsor: **IPSEN, Inc.** Date Designated: **9/11/2000**
Address: **27 Maple Street** Market Approval Date: **Not currently Approved**
Milford MA 01757

Generic Name: **Latrodectus immune F(ab)2** Trade Name: **Aracmyn**
Designated Indication: *Treatment of black widow spider envenomations*
Sponsor: **Rare Disease Therapeutics, Inc.** Date Designated: **6/18/2001**
Address: **1101 Kermit Drive, Suite 608** Market Approval Date: **Not currently Approved**
Nashville TN 37217

Generic Name: **Leflunomide** Trade Name: **NONE ASSIGNED**
Designated Indication: *Prevention of acute and chronic rejection in patients who have received solid organ transplants.*
Sponsor: **Williams, MD, James W.** Date Designated: **10/18/1996**
Address: **Rush-Presbyterian-St. Luke's Medical Ctr.,** Market Approval Date: **Not currently Approved**
1653 West Congress Parkway
Chicago IL 60612-3833

Generic Name: **Lepirudin** Trade Name: **Refluden**
Designated Indication: *Treatment of heparin-associated thrombocytopenia type II.*
Sponsor: **Hoechst Marion Roussel** Date Designated: **2/13/1997**
Address: **Frankfurt am Main** Market Approval Date: **3/6/1998**
Germany DE

Generic Name: **Leucovorin** Trade Name: **Leucovorin calcium**
Designated Indication: *For rescue use after high dose methotrexate therapy in the treatment of osteosarcoma.*
Sponsor: **Immunex Corporation** Date Designated: **8/17/1988**
Address: **51 University Street** Market Approval Date: **8/31/1988**
Seattle WA 98101

Generic Name: **Leucovorin** Trade Name: **Leucovorin calcium**

Designated Indication: *For use in combination with 5-fluorouracil for the treatment of metastatic colorectal cancer.*

Sponsor: **Immunex Corporation** Date Designated: **12/8/1986**
Address: **51 University Street** Market Approval Date: **12/12/1991**
Seattle WA 98101

Generic Name: **Leupeptin** Trade Name: **NONE ASSIGNED**

Designated Indication: *For use as an adjunct to microsurgical peripheral nerve repair.*

Sponsor: **Neuromuscular Adjuncts, Inc.** Date Designated: **9/18/1990**
Address: **S.U.N.Y. at Stony Brook** Market Approval Date: **Not currently Approved**
H.S.C. T18-020
Stony Brook NY 11794-8181

Generic Name: **Leuprolide acetate** Trade Name: **Lupron Injection**

Designated Indication: *Treatment of central precocious puberty.*

Sponsor: **Tap Pharmaceuticals, Inc.** Date Designated: **7/25/1988**
Address: **2355 Waukegan Road** Market Approval Date: **4/16/1993**
Deerfield IL 60015

Generic Name: **Levocarnitine** Trade Name: **Carnitor**

Designated Indication: *For the treatment of secondary carnitine deficiency in valproic acid toxicity.*

Sponsor: **Sigma-Tau Pharmaceuticals, Inc.** Date Designated: **11/15/1989**
Address: **800 South Frederick Avenue** Market Approval Date: **Not currently Approved**
Gaithersburg MD 20877

Generic Name: **Levocarnitine** Trade Name: **Carnitor**

Designated Indication: *Treatment of zidovudine-induced mitochondrial myopathy.*

Sponsor: **Sigma-Tau Pharmaceuticals, Inc.** Date Designated: **4/7/1997**
Address: **800 S. Frederick Avenue, Suite 300** Market Approval Date: **Not currently Approved**
Gaithersburg MD 20877

Generic Name: **Levocarnitine** Trade Name: **Carnitor**
Designated Indication: *Treatment of pediatric cardiomyopathy.*
Sponsor: **Sigma-Tau Pharmaceuticals, Inc.** Date Designated: **11/22/1993**
Address: **800 South Frederick Avenue** Market Approval Date: **Not currently Approved**
Gaithersburg MD 20877

Generic Name: **Levocarnitine** Trade Name: **Carnitor**
Designated Indication: *Treatment of primary and secondary carnitine deficiency of genetic origin.*
Sponsor: **Sigma-Tau Pharmaceuticals, Inc.** Date Designated: **7/26/1984**
Address: **800 South Frederick Avenue** Market Approval Date: **12/16/1992**
Gaithersburg MD 20877

Generic Name: **Levocarnitine** Trade Name: **Carnitor**
Designated Indication: *Treatment of manifestations of carnitine deficiency in patients with end stage renal disease who require dialysis.*
Sponsor: **Sigma-Tau Pharmaceuticals, Inc.** Date Designated: **9/6/1988**
Address: **800 South Frederick Avenue, Suite 300** Market Approval Date: **12/15/1999**
Gaithersburg MD 20877

Generic Name: **Levocarnitine** Trade Name: **Carnitor**
Designated Indication: *Treatment of genetic carnitine deficiency.*
Sponsor: **Sigma-Tau Pharmaceuticals, Inc.** Date Designated: **2/28/1984**
Address: **800 South Frederick Avenue** Market Approval Date: **4/10/1986**
Gaithersburg MD 20877

Generic Name: **Levocarnitine** Trade Name: **Carnitor**
Designated Indication: *For the prevention of secondary carnitine deficiency in valproic acid toxicity.*
Sponsor: **Sigma-Tau Pharmaceuticals, Inc.** Date Designated: **11/15/1989**
Address: **800 South Frederick Avenue** Market Approval Date: **Not currently Approved**
Gaithersburg MD 20877

Generic Name: **Levodopa and carbidopa**

Trade Name: **Duodopa**

Designated Indication: *Treatment of late stage Parkinson's disease.*

Sponsor: **Nouvel Pharma, Inc.**
Address: **11384 Strang Line Road
Lenexa KS 66215**

Date Designated: **1/18/2000**
Market Approval Date: **Not currently Approved**

Generic Name: **Levomethadyl acetate hydrochloride**

Trade Name: **Orlaam**

Designated Indication: *Treatment of heroin addicts suitable for maintenance on opiate agonists.*

Sponsor: **Biodevelopment Corporation**
Address: **8180 Greensboro Drive, Suite 1000
McLean VA 22102**

Date Designated: **1/24/1985**
Market Approval Date: **7/9/1993**

Generic Name: **Lidocaine patch 5%**

Trade Name: **Lidoderm Patch**

Designated Indication: *For relief of allodynia (painful hypersensitivity), and chronic pain in post-herpetic neuralgia.*

Sponsor: **Teikoku Pharma USA, Inc.**
Address: **745-D Camden Ave.
Campbell CA 95008-4146**

Date Designated: **10/24/1995**
Market Approval Date: **3/19/1999**

Generic Name: **Liothyronine sodium injection**

Trade Name: **Triostat**

Designated Indication: *Treatment of myxedema coma/precoma.*

Sponsor: **SmithKline Beecham Pharmaceuticals**
Address: **One Franklin Plaza
P.O. Box 7929
Philadelphia PA 19101**

Date Designated: **7/30/1990**
Market Approval Date: **12/31/1991**

Generic Name: **Lipid/DNA human cystic fibrosis gene**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of cystic fibrosis.*

Sponsor: **Genzyme Corporation**
Address: **One Mountain Road
P.O. Box 9322
Framingham MA 01701-9322**

Date Designated: **4/8/1996**
Market Approval Date: **Not currently Approved**

Generic Name: **Liposomal amphotericin B**

Trade Name: **AmBisome**

Designated Indication: *Treatment of cryptococcal meningitis.*

Sponsor: **Fujisawa USA, Inc.**
Address: **3 Parkway North Center
Deerfield IL 60015**

Date Designated: **12/10/1996**
Market Approval Date: **8/11/1997**

Generic Name: **Liposomal amphotericin B**

Trade Name: **AmBisome**

Designated Indication: *Treatment of visceral leishmaniasis.*

Sponsor: **Fujisawa USA, Inc.**
Address: **3 Parkway North Center
Deerfield IL 60015**

Date Designated: **12/6/1996**
Market Approval Date: **8/11/1997**

Generic Name: **Liposomal amphotericin B**

Trade Name: **AmBisome**

Designated Indication: *Treatment of histoplasmosis.*

Sponsor: **Fujisawa USA, Inc.**
Address: **3 Parkway North Center
Deerfield IL 60015**

Date Designated: **12/10/1996**
Market Approval Date: **Not currently Approved**

Generic Name: **Liposomal cyclosporin A**

Trade Name: **Cyclospire**

Designated Indication: *For aerosolized administration in the prevention and treatment of lung allograft rejection and pulmonary rejection events associated with bone marrow transplantation.*

Sponsor: **Vernon Knight, M.D.**
Address: **Baylor College of Medicine, Dept. of
One Baylor Plaza
Houston TX 77030**

Date Designated: **4/30/1998**
Market Approval Date: **Not currently Approved**

Generic Name: **Liposomal N-Acetylglucosminyl-N-Acetylmuramly-L-Ala-D-isoGln-**

Trade Name: **ImmTher**

Designated Indication: *Treatment of Ewing's sarcoma.*

Sponsor: **Endorex Corp.**
Address: **900 North Shore Drive
Lake Bluff IL 60044**

Date Designated: **6/10/1998**
Market Approval Date: **Not currently Approved**

Generic **Liposomal** Trade ImmTher
Name: **N-Acetylglucosminyl-N-Acetylmuramyl-L-Ala-D-isoGln-** Name:
Designated *Treatment of osteosarcoma.*
Indication:
Sponsor: Endorex Corp. Date Designated: 6/10/1998
Address: 900 North Shore Drive Market Approval Date: Not currently Approved
Lake Bluff IL 60044

Generic **Liposomal nystatin** Trade Nyotran
Name: Name:
Designated *Treatment of invasive fungal infections.*
Indication:
Sponsor: Aronex Pharmaceuticals, Inc. Date Designated: 6/13/2000
Address: 8707 Technology Forest Place Market Approval Date: Not currently Approved
The Woodlands TX 77381-1191

Generic **Liposomal-cis-bis-neodecanoato-trans-R,R-1,2-diaminoc** Trade NONE ASSIGNED
Name: **yclohexane-Pt (II)** Name:
Designated *Treatment of malignant mesothelioma.*
Indication:
Sponsor: Antigenics Incorporated Date Designated: 9/1/1999
Address: 34 Commerce Way Market Approval Date: Not currently Approved
Woburn MA 01801

Generic **Liposome encapsulated recombinant interleukin-2** Trade NONE ASSIGNED
Name: Name:
Designated *Treatment of cancers of the kidney and renal pelvis.*
Indication:
Sponsor: Biomira USA, Inc. Date Designated: 6/20/1994
Address: 1002 Eastpark Boulevard Market Approval Date: Not currently Approved
Cranbury NJ 08512

Generic **Liposome encapsulated recombinant interleukin-2** Trade NONE ASSIGNED
Name: Name:
Designated *Treatment of brain and CNS tumors.*
Indication:
Sponsor: Biomira USA, Inc. Date Designated: 11/25/1991
Address: 1002 Eastpark Boulevard Market Approval Date: Not currently Approved
Cranbury NJ 08512

Generic Name: **Lisofylline** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of patients undergoing induction therapy for acute myeloid leukemia.*
Sponsor: Cell Therapeutics, Inc. Date Designated: 6/10/1999
Address: 201 Elliot Avenue West Market Approval Date: Not currently Approved
Suite 400
Seattle WA 98119

Generic Name: **Lodoxamide tromethamine** Trade Name: **Alomide Ophthalmic Solution**
Designated Indication: *Treatment of vernal keratoconjunctivitis.*
Sponsor: Alcon Laboratories, Inc. Date Designated: 10/16/1991
Address: 6201 South Freeway Market Approval Date: 9/23/1993
Fort Worth TX 76134

Generic Name: **Lucinactant** Trade Name: **Surfaxin**
Designated Indication: *Treatment of acute respiratory distress syndrome in adults.*
Sponsor: Discovery Laboratories, Inc. Date Designated: 7/17/1995
Address: 350 South Main Street Market Approval Date: Not currently Approved
Suite 307
Doylestown PA 18901

Generic Name: **Lucinactant** Trade Name: **Surfaxin**
Designated Indication: *Treatment of meconium aspiration syndrome in newborn infants.*
Sponsor: Discovery Laboratories, Inc. Date Designated: 7/30/1996
Address: 350 South Main Street Market Approval Date: Not currently Approved
Suite 307
Doylestown PA 18901

Generic Name: **Lucinactant** Trade Name: **Surfaxin**
Designated Indication: *Treatment of respiratory distress syndrome in premature infants.*
Sponsor: Discovery Laboratories, Inc. Date Designated: 10/18/1995
Address: 350 South Main Street Market Approval Date: Not currently Approved
Suite 307
Doylestown PA 18901

Generic Name: **Mafenide acetate solution** Trade Name: **Sulfamylon solution**
Designated Indication: *For use as an adjunctive topical antimicrobial agent to control bacterial infection when used under moist dressings over meshed autografts on excised burn wounds.*
Sponsor: **Mylan Laboratories, Inc.** Date Designated: **7/18/1990**
Address: **781 Chestnut Ridge Road** Market Approval Date: **6/5/1998**
P.O. Box 4310
Morgantown WV 26504-4310

Generic Name: **Marijuana** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of HIV-associated wasting syndrome.*
Sponsor: **Multidisciplinary Association for** Date Designated: **5/25/1999**
Address: **3 Francis St.** Market Approval Date: **Not currently Approved**
Belmont MA 02478

Generic Name: **MART-1 adenoviral gene therapy for malignant melanoma** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of metastatic melanoma.*
Sponsor: **Genzyme Corporation** Date Designated: **3/28/1997**
Address: **One Mountain Road** Market Approval Date: **Not currently Approved**
P.O. Box 9322
Framingham MA 01701-9322

Generic Name: **Matrix metalloproteinase inhibitor** Trade Name: **Galardin**
Designated Indication: *Treatment of corneal ulcers.*
Sponsor: **Glycomed, Inc** Date Designated: **12/5/1991**
Address: **860 Atlantic Avenue** Market Approval Date: **Not currently Approved**
Alameda CA 94501

Generic Name: **Mazindol** Trade Name: **Sanorex**
Designated Indication: *Treatment of Duchenne muscular dystrophy.*
Sponsor: **Collipp, Platon J. M.D.** Date Designated: **12/8/1986**
Address: **176 Memorial Drive** Market Approval Date: **Not currently Approved**
Jesup GA 31545

Generic Name: **Mecamylamine** Trade Name: **Inversine**
Designated Indication: *Treatment of Tourette's syndrome.*
Sponsor: Layton Bioscience, Inc. Date Designated: 10/14/1998
Address: 709 E. Evelyn Avenue Market Approval Date: Not currently Approved
Sunnyvale CA 94086

Generic Name: **Mecasermin** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of growth hormone insufficiency syndrome.*
Sponsor: Genentech, Inc. Date Designated: 12/12/1995
Address: 460 Point San Bruno Boulevard Market Approval Date: Not currently Approved
South San Francisco CA 94080

Generic Name: **Mecasermin** Trade Name: **Myotrophin**
Designated Indication: *Treatment of amyotrophic lateral sclerosis.*
Sponsor: Cephalon, Inc. Date Designated: 8/5/1991
Address: 145 Brandywine Parkway Market Approval Date: Not currently Approved
West Chester PA 19380-4245

Generic Name: **Medroxyprogesterone acetate** Trade Name: **Hematrol**
Designated Indication: *Treatment of immune thrombocytopenic purpura.*
Sponsor: InKine Pharmaceutical Company, Inc. Date Designated: 2/22/2001
Address: 1787 Sentry Parkway West Market Approval Date: Not currently Approved
Building 18, Suite 440
Blue Bell PA 19422

Generic Name: **Mefloquine HCl** Trade Name: **Lariam**
Designated Indication: *Treatment of acute malaria due to Plasmodium falciparum and Plasmodium vivax.*
Sponsor: Hoffmann-La Roche, Inc. Date Designated: 4/13/1988
Address: 340 Kingsland Street Market Approval Date: 5/2/1989
Nutley NJ 07110

Generic Name: **Mefloquine HCl** Trade Name: **Mephaquin**
Designated Indication: *Treatment of chloroquine-resistant Falciparum malaria.*
Sponsor: **Mepha AG** Date Designated: **7/22/1987**
Address: **4143 Dornach** Market Approval Date: **Not currently Approved**
POSTFASH 137
Aesch Basel, Switzerland CH

Generic Name: **Mefloquine HCl** Trade Name: **Lariam**
Designated Indication: *Prophylaxis of Plasmodium falciparum malaria which is resistant to other available drugs.*
Sponsor: **Hoffmann-La Roche, Inc.** Date Designated: **4/13/1988**
Address: **340 Kingsland Street** Market Approval Date: **5/2/1989**
Nutley NJ 07110

Generic Name: **Mefloquine HCl** Trade Name: **Mephaquin**
Designated Indication: *Prevention of chloroquine-resistant Falciparum malaria.*
Sponsor: **Mepha AG** Date Designated: **7/22/1987**
Address: **4143 Dornach** Market Approval Date: **Not currently Approved**
POSTFASH 137
Aesch Basel, Switzerland CH

Generic Name: **Megestrol acetate** Trade Name: **Megace**
Designated Indication: *Treatment of patients with anorexia, cachexia, or significant weight loss ($\geq 10\%$ of baseline body weight) and confirmed diagnosis of AIDS.*
Sponsor: **Bristol-Myers Squibb Pharmaceutical** Date Designated: **4/13/1988**
Address: **2400 West Lloyd Expressway** Market Approval Date: **9/10/1993**
Evansville IN 47721

Generic Name: **Melanoma cell vaccine** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of invasive melanoma.*
Sponsor: **Morton, Donald L. M.D.** Date Designated: **10/13/1994**
Address: **John Wayne Cancer Institute** Market Approval Date: **Not currently Approved**
2200 Santa Monica Boulevard
Santa Monica CA 90404

Generic Name: **Melanoma vaccine** Trade Name: **Melacine**
Designated Indication: *Treatment of stage III - IV melanoma.*
Sponsor: **Ribi ImmunoChem Research, Inc.** Date Designated: **12/20/1989**
Address: **533 Old Corvallis Road** Market Approval Date: **Not currently Approved**
Hamilton MT 59840

Generic Name: **Melatonin** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of circadian rhythm sleep disorders in blind people with no light perception.*
Sponsor: **Sack, Robert, M.D.** Date Designated: **11/15/1993**
Address: **Oregon Health Sciences University** Market Approval Date: **Not currently Approved**
3181 S.W. Sam Jackson Park Road
Portland OR 97201

Generic Name: **Meropenem** Trade Name: **Merrem IV**
Designated Indication: *Management of acute pulmonary exacerbations, in cystic fibrosis patients, due to respiratory tract infection with susceptible organisms.*
Sponsor: **Zeneca Pharmaceuticals** Date Designated: **4/27/2000**
Address: **1800 Concord Pike** Market Approval Date: **Not currently Approved**
PO Box 15437
Wilmington DE 19850-5437

Generic Name: **Mesna** Trade Name: **NONE ASSIGNED**
Designated Indication: *Inhibition of the urotoxic effects induced by oxazaphosphorine compounds such as cyclophosphamide.*
Sponsor: **Asta Medica, Inc.** Date Designated: **12/16/1987**
Address: **890 East St.** Market Approval Date: **Not currently Approved**
Tewksbury MA 01876-1496

Generic Name: **Mesna** Trade Name: **Mesnex**
Designated Indication: *For use as a prophylactic agent in reducing the incidence of ifosfamide-induced hemorrhagic cystitis.*
Sponsor: **Degussa Corporation** Date Designated: **11/14/1985**
Address: **65 Challenger Road** Market Approval Date: **12/30/1988**
Ridgefield Park NJ 07660

Generic Name: **Methionine/L-methionine** Trade Name: NONE ASSIGNED
Designated Indication: *Treatment of AIDS myelopathy.*
Sponsor: Di Rocco, Alessandro M.D. Date Designated: 8/21/1996
Address: Beth Israel Medical Center, Phillips
Philips Building, Suite 2R; 10 Union Square
New York NY 10003 Market Approval Date: Not currently Approved

Generic Name: **Methotrexate sodium** Trade Name: Methotrexate
Designated Indication: *Treatment of osteogenic sarcoma.*
Sponsor: Lederle Laboratories Date Designated: 10/21/1985
Address: Division of American Cyanamid Company
401 N. Middletown Road
Pearl River NY 10965 Market Approval Date: 4/7/1988

Generic Name: **Methotrexate with laurocapram** Trade Name: Methotrexate/azone
Designated Indication: *Topical treatment of mycosis fungoides.*
Sponsor: Durham Pharmaceuticals LLC Date Designated: 10/15/1990
Address: 200 Westpark Corporate Center
4364 South Alston Avenue
Durham NC 27713-2280 Market Approval Date: Not currently Approved

Generic Name: **Methoxsalen** Trade Name: Uvadex
Designated Indication: *For use in conjunction with the UVAR photopheresis system to treat graft versus host disease.*
Sponsor: Therakos, Inc. Date Designated: 10/14/1998
Address: 437 Creamery Way
Exton PA 19431 Market Approval Date: Not currently Approved

Generic Name: **metreleptin** Trade Name: NONE ASSIGNED
Designated Indication: *Treatment of leptin deficiency secondary to generalized lipodystrophy and partial familial lipodystrophy*
Sponsor: Amgen, Inc. Date Designated: 8/22/2001
Address: One Amgen Center Drive
Thousand Oaks CA 91320-1799 Market Approval Date: Not currently Approved

Generic Name: **metreleptin** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of metabolic disorders secondary to lipodystrophy*
Sponsor: **Amgen, Inc.,** Date Designated: **8/22/2001**
Address: **One Amgen Center Drive** Market Approval Date: **Not currently Approved**
Thousand Oaks CA 91320-1799

Generic Name: **Metronidazole** Trade Name: **Metrogel**
Designated Indication: *Treatment of perioral dermatitis.*
Sponsor: **Galderma Laboratories, Inc.** Date Designated: **10/24/1991**
Address: **P.O. Box 331329** Market Approval Date: **Not currently Approved**
Fort Worth TX 76163

Generic Name: **Metronidazole (topical)** Trade Name: **Metrogel**
Designated Indication: *Treatment of acne rosacea.*
Sponsor: **Galderma Laboratories, Inc.** Date Designated: **10/22/1987**
Address: **P.O. Box 331329** Market Approval Date: **11/22/1988**
Fort Worth TX 76163

Generic Name: **Microbubble contrast agent** Trade Name: **Filmix Neurosonographic Contrast Agent**
Designated Indication: *Intraoperative aid in the identification and localization of intracranial tumors.*
Sponsor: **Cav-Con, Inc.** Date Designated: **11/16/1990**
Address: **55 Knollwood Road** Market Approval Date: **Not currently Approved**
Farmington CT 06032

Generic Name: **Midodrine HCl** Trade Name: **Amatine**
Designated Indication: *Treatment of patients with symptomatic orthostatic hypotension.*
Sponsor: **Schier Ridgewood F.K.A. (Roberts)** Date Designated: **12/5/1996**
Address: **Meridian Center III** Market Approval Date: **9/6/1996**
6 Industrial Way West
Eatontown NJ 07724

Generic Name: **Mitoguazone** Trade Name: **a pep**
Designated Indication: *Treatment of diffuse non-Hodgkin's lymphoma, including AIDS-related diffuse non-Hodgkin's lymphoma.*
Sponsor: **ILEX Oncology, Inc.** Date Designated: **3/18/1994**
Address: **4545 Horizon Hill Blvd.** Market Approval Date: **Not currently Approved**
San Antonio TX 78229-2263

Generic Name: **Mitolactol** Trade Name: **NONE ASSIGNED**
Designated Indication: *As adjuvant therapy in the treatment of primary brain tumors.*
Sponsor: **Biopharmaceutics, Inc.** Date Designated: **7/12/1995**
Address: **990 Station Road** Market Approval Date: **Not currently Approved**
Bellport NY 11713

Generic Name: **Mitolactol** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of recurrent invasive or metastatic squamous carcinoma of the cervix.*
Sponsor: **Biopharmaceutics, Inc.** Date Designated: **1/23/1989**
Address: **990 Station Road** Market Approval Date: **Not currently Approved**
Bellport NY 11713

Generic Name: **Mitomycin-C** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of refractory glaucoma as an adjunct to ab externo glaucoma surgery.*
Sponsor: **IOP Inc.** Date Designated: **8/20/1993**
Address: **3100 Airway Avenue, Suite 106** Market Approval Date: **Not currently Approved**
Costa Mesa CA 92626

Generic Name: **Mitoxantrone** Trade Name: **Novantrone**
Designated Indication: *Treatment of hormone refractory prostate cancer.*
Sponsor: **Immunex Corporation** Date Designated: **8/21/1996**
Address: **51 University Street** Market Approval Date: **11/13/1996**
Seattle WA 98101

Generic Name: **Mitoxantrone** Trade Name: **Novantrone**
Designated Indication: *Treatment of progressive-relapsing multiple sclerosis.*
Sponsor: Immunex Corporation Date Designated: 8/13/1999
Address: 51 University St. Market Approval Date: 10/13/2000
Seattle WA 98101

Generic Name: **Mitoxantrone** Trade Name: **Novantrone**
Designated Indication: *Treatment of secondary-progressive multiple sclerosis.*
Sponsor: Immunex Corporation Date Designated: 8/13/1999
Address: 51 University St. Market Approval Date: 10/13/2000
Seattle WA 98101

Generic Name: **Mitoxantrone HCl** Trade Name: **Novantrone**
Designated Indication: *Treatment of acute myelogenous leukemia, also referred to as acute nonlymphocytic leukemia.*
Sponsor: Lederle Laboratories Date Designated: 7/13/1987
Address: Division of American Cyanamid Company Market Approval Date: 12/23/1987
401 N. Middletown Road
Pearl River NY 10965

Generic Name: **MN14 monoclonal antibody to carcinoembryonic antigen** Trade Name: **Cea-Cide**
Designated Indication: *Treatment of pancreatic cancer.*
Sponsor: Immunomedics, Inc. Date Designated: 11/24/1998
Address: 300 American Road Market Approval Date: Not currently Approved
Morris Plains NJ 07950

Generic Name: **MN14 monoclonal antibody to carcinoembryonic antigen** Trade Name: **Cea-Cide**
Designated Indication: *For the treatment of small cell lung cancer.*
Sponsor: Immunomedics, Inc. Date Designated: 9/18/1998
Address: 300 American Rd. Market Approval Date: Not currently Approved
Morris Plains NJ 07950

Generic Name: **Modafinil**

Trade Name: **Provigil**

Designated Indication: *Treatment of excessive daytime sleepiness in narcolepsy.*

Sponsor: **Cephalon, Inc.**
Address: **145 Brandywine Parkway
West Chester PA 19380**

Date Designated: **3/15/1993**
Market Approval Date: **12/24/1998**

Generic Name: **Monoclonal antibodies PM-81 and AML-2-23**

Trade Name: **NONE ASSIGNED**

Designated Indication: *For the exogenous depletion of CD14 and CD15 positive acute myeloid leukemic bone marrow cells from patients undergoing bone marrow transplantation.*

Sponsor: **Medarex, Inc.**
Address: **67 Beaver Avenue
Annandale NJ 08801-0953**

Date Designated: **3/12/1990**
Market Approval Date: **Not currently Approved**

Generic Name: **Monoclonal antibody for immunization against lupus nephritis**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of lupus nephritis.*

Sponsor: **VivoRx Autoimmune, Inc.**
Address: **2825 Santa Monica Blvd., Suite 200
Santa Monica CA 90404**

Date Designated: **1/7/1993**
Market Approval Date: **Not currently Approved**

Generic Name: **Monoclonal antibody PM-81**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Adjunctive treatment of acute myelogenous leukemia.*

Sponsor: **Medarex, Inc.**
Address: **519 Route 173 West
Bloomsbury NJ 08804**

Date Designated: **6/27/1991**
Market Approval Date: **Not currently Approved**

Generic Name: **Monoclonal antibody-B43.13**

Trade Name: **Ovarex MAb-B43.13**

Designated Indication: *Treatment of epithelial ovarian cancer.*

Sponsor: **AltaRex US Corp.**
Address: **610 Lincoln Street
Waltham MA 02451**

Date Designated: **11/25/1996**
Market Approval Date: **Not currently Approved**

Generic Name: **Monolaurin** Trade Name: **Glylorin**
Designated Indication: *Treatment of congenital primary ichthyosis.*
Sponsor: Glaxo Wellcome Inc. Date Designated: 4/29/1993
Address: 5 Moore Drive Market Approval Date: Not currently Approved
PO Box 13398
Research Triangle Park NC 27709

Generic Name: **Monoctanoin** Trade Name: **Moctanin**
Designated Indication: *For dissolution of cholesterol gallstones retained in the common bile duct.*
Sponsor: Ethitek Pharmaceuticals, Inc. Date Designated: 5/30/1984
Address: 7855 Gross Point Road, Unit L Market Approval Date: 10/31/1985
Skokie IL 60077

Generic Name: **Morphine sulfate concentrate (preservative free)** Trade Name: **Infumorph**
Designated Indication: *For use in microinfusion devices for intraspinal administration in the treatment of intractable chronic pain.*
Sponsor: Elkins-Sinn, Inc. Date Designated: 7/12/1990
Address: 2 Esterbrook Lane Market Approval Date: 7/19/1991
Cherry Hill NJ 08003

Generic Name: **MTC-DOX for Injection** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of hepatocellular carcinoma*
Sponsor: FeRx Incorporated Date Designated: 1/3/2001
Address: 4330 La Jolla Village Drive Market Approval Date: Not currently Approved
Suite #250
San Diego CA 92122

Generic Name: **Multi-vitamin infusion (neonatal formula)** Trade Name: **NONE ASSIGNED**
Designated Indication: *For establishment and maintenance of total parenteral nutrition in very low birth weight infants.*
Sponsor: Astra Pharmaceuticals, L.P. Date Designated: 12/12/1989
Address: 725 Chesterbrook Blvd. Market Approval Date: Not currently Approved
Wayne PA 19087-5677

Generic Name: **muramyltriptide, phosphatidyl-ethanolamine encased in multi-lamellar liposomes** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of children and adolescent osteosarcoma*
Sponsor: Jenner Biotherapies, Inc. Date Designated: 6/5/2001
Address: 541 Kenosa Street Market Approval Date: Not currently Approved
Walworth WI 53184

Generic Name: **Murine MAb (Lym-1) and Iodine 131-I radiolabeled murine MAb (Lym-1) to human B-cell lymphoma** Trade Name: **Oncolym**
Designated Indication: *Treatment of B-cell non-Hodgkin's lymphoma.*
Sponsor: Berlex Laboratories Date Designated: 11/27/1998
Address: 15049 San Pablo Ave. Market Approval Date: Not currently Approved
PO Box 4099
Richmond CA 94804-0099

Generic Name: **Murine MAb to polymorphic epithelial mucin, human milk fat globule 1** Trade Name: **Theragyn**
Designated Indication: *Adjuvant treatment of ovarian cancer.*
Sponsor: Antisoma plc Date Designated: 3/22/1999
Address: West Africa House Market Approval Date: Not currently Approved
Hanger Lane Ealing
London W5 3QR UK

Generic Name: **Mycobacterium avium sensitin RS-10** Trade Name: **NONE ASSIGNED**
Designated Indication: *For use in the diagnosis of invasive Mycobacterium avium disease in immunocompetent individuals.*
Sponsor: Statens Seruminstitut Date Designated: 10/11/1995
Address: 5 Artillerivej Market Approval Date: Not currently Approved
DK-2300 Copenhagen S
Denmark

Generic Name: **N-acetyl-procainamide** Trade Name: **NONE ASSIGNED**
Designated Indication: *Prevention of life-threatening ventricular arrhythmias in patients with documented procainamide-induced lupus.*
Sponsor: NAPA of the Bahamas Date Designated: 12/10/1996
Address: 3560 Pennsylvania Avenue, Suite 7 Market Approval Date: Not currently Approved
Dubuque IA 52002

Generic Name: **N-acetylcysteinate** Trade Name: **Nacystelyn Dry Powder Inhaler**
Designated Indication: *For the management of cystic fibrosis*
Sponsor: **Galephar Pharmaceutical Research, Inc.** Date Designated: **12/27/2000**
Address: **Road 198, No. 100 km. 14.7** Market Approval Date: **Not currently Approved**
Juncos Industrial Park
Juncos PR 00777-3873

Generic Name: **N-acetylgalactosamine-4-sulfatase, recombinant human** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of mucopolysaccharidosis Type VI (Maroteaux-Lamy syndrome).*
Sponsor: **BioMarin Pharmaceutical, Inc.** Date Designated: **2/17/1999**
Address: **11 Pimental Court** Market Approval Date: **Not currently Approved**
Novato CA 94949-5608

Generic Name: **Nafarelin acetate** Trade Name: **Synarel Nasal Solution**
Designated Indication: *Treatment of central precocious puberty.*
Sponsor: **Syntex (USA), Inc.** Date Designated: **7/20/1988**
Address: **3401 Hillview Avenue** Market Approval Date: **Not currently Approved**
Palo Alto CA 94303

Generic Name: **Naltrexone HCl** Trade Name: **Trexan**
Designated Indication: *For blockade of the pharmacological effects of exogenously administered opioids as an adjunct to the maintenance of the opioid-free state in detoxified formerly opioid-dependent individuals.*
Sponsor: **DuPont Pharmaceuticals** Date Designated: **3/11/1985**
Address: **E.I. Du Pont De Nemours & Co.** Market Approval Date: **11/30/1984**
Wilmington DE 19880

Generic Name: **Natural human lymphoblastoid interferon-alpha** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of papillomavirus warts in the oral cavity of HIV positive patients.*
Sponsor: **Amarillo Biosciences, Inc.** Date Designated: **8/10/2000**
Address: **800 West 9th Avenue** Market Approval Date: **Not currently Approved**
Amarillo TX 79101-3206

Generic **Natural human lymphoblastoid interferon-alpha**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of Behcet's disease.*
Indication:

Sponsor: Amarillo Biosciences, Inc.
Address: 800 West Ninth Avenue
Amarillo TX 79101-3206

Date Designated: 1/18/2000
Market Approval Date: Not currently Approved

Generic **NDROGE**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of postanoxic intention myoclonus.*
Indication:

Sponsor: WATSON Laboratories, Inc.
Address: 33 Ralph Avenue
P.O. Box 30
Copiague NY 11726-0030

Date Designated: 11/1/1984
Market Approval Date: Not currently Approved

Generic **Nebacumab**
Name:

Trade **Centoxin**
Name:

Designated *Treatment of patients with gram-negative bacteremia which has progressed to endotoxin shock.*
Indication:

Sponsor: Centocor, Inc.
Address: 200 Great Valley Parkway
Malvern PA 19355

Date Designated: 10/1/1986
Market Approval Date: Not currently Approved

Generic **Neurotrophin-1**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of motor neuron disease/amyotrophic lateral sclerosis.*
Indication:

Sponsor: Ericsson, Arthur Dale, M.D.
Address: 6560 Fannin, Scurlock Tower, Suite 720
Houston TX 77303

Date Designated: 9/13/1994
Market Approval Date: Not currently Approved

Generic **NG-29**
Name:

Trade **Somatrel**
Name:

Designated *Diagnostic measure of the capacity of the pituitary gland to release growth hormone.*
Indication:

Sponsor: Ferring Laboratories, Inc.
Address: 400 Rella Boulevard, Suite 201
Suffern NY 10901

Date Designated: 8/8/1989
Market Approval Date: Not currently Approved

Generic **Nifedipine**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of interstitial cystitis.*
Indication:

Sponsor: Fleischmann, Jonathan M.D.
Address: MetroHealth Medical Center
3395 Scranton Road
Cleveland OH 44109

Date Designated: 6/13/1991
Market Approval Date: Not currently Approved

Generic **nitazoxanide**
Name:

Trade **Cryptaz**
Name:

Designated *Treatment for intestinal amebiasis*
Indication:

Sponsor: Romark Laboratories, L.C.
Address: 6200 Courtney Campbell Causeway
Suite 880
Tampa FL 33607

Date Designated: 10/23/2001
Market Approval Date: Not currently Approved

Generic **Nitazoxanide**
Name:

Trade **Cryptaz**
Name:

Designated *Treatment of cryptosporidiosis.*
Indication:

Sponsor: Romark Laboratories, L.C.
Address: 6200 Courtney Campbell Causeway
Suite 880
Tampa FL 33607

Date Designated: 12/12/1996
Market Approval Date: Not currently Approved

Generic **Nitisinone**
Name:

Trade **Orfadin**
Name:

Designated *Treatment of tyrosinemia type 1.*
Indication:

Sponsor: Swedish Orphan AB
Address: Drottninggatan 98
SE-111 60 Stockholm
Sweden SE

Date Designated: 5/16/1995
Market Approval Date: Not currently Approved

Generic **Nitisinone**
Name:

Trade **Orfadin**
Name:

Designated *Treatment of alkaptonuria*
Indication:

Sponsor: Swedish Orphan AB
Address: Kungsgatan 37, 7th Floor
SE-111 56
Stockholm, Sweden

Date Designated: 10/19/2001
Market Approval Date: Not currently Approved

Generic Name: **Nitric oxide** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of acute respiratory distress syndrome in adults.*
Sponsor: **INO Therapeutics, Inc.** Date Designated: **7/10/1995**
Address: **54 Old Highway 22** Market Approval Date: **Not currently Approved**
Clinton NJ 08809

Generic Name: **Nitric oxide** Trade Name: **INOMax**
Designated Indication: *Treatment of persistent pulmonary hypertension in the newborn.*
Sponsor: **INO Therapeutics, Inc.** Date Designated: **6/22/1993**
Address: **54 Old Highway 22** Market Approval Date: **12/23/1999**
Clinton NJ 08809

Generic Name: **Nitroprusside** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment and prevention of cerebral vasospasm following subarachnoid hemorrhage.*
Sponsor: **Thomas, MD, Jeffrey Evan** Date Designated: **2/21/2001**
Address: **Thomas Jefferson University and Wills** Market Approval Date: **Not currently Approved**
834 Walnut Street, Suite 650
Philadelphia PA 19107-5102

Generic Name: **nolatrexed** Trade Name: **THYMITAQ**
Designated Indication: *Treatment of hepatocellular carcinoma*
Sponsor: **Zarix, Inc.** Date Designated: **10/18/2001**
Address: **1055 Westlakes Drive** Market Approval Date: **Not currently Approved**
Suite 200
Berwyn PA 19312

Generic Name: **Novel Acting Thrombolytic (NAT)** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of peripheral arterial occlusion (PAO)*
Sponsor: **Amgen, Inc.** Date Designated: **1/26/2001**
Address: **One Amgen Center Drive** Market Approval Date: **Not currently Approved**
Thousand Oaks CA 91320-1799

Generic Name: **NZ-1002** Trade Name: **NONE ASSIGNED**
Designated Indication: *Enzyme replacement therapy in patients with all subtypes of Mucopolysaccharidosis I.*
Sponsor: Novazyme Pharmaceuticals, Inc. Date Designated: 4/11/2001
Address: 800 Research Parkway Market Approval Date: Not currently Approved
Suite 200
Oklahoma City OK 73104

Generic Name: **Octreotide** Trade Name: **Sandostatin LAR**
Designated Indication: *Treatment of acromegaly.*
Sponsor: Novartis Pharmaceuticals Corporation Date Designated: 8/24/1998
Address: 59 Route 10 Market Approval Date: 11/25/1998
East Hanover NJ 07936-1080

Generic Name: **Octreotide** Trade Name: **Sandostatin LAR**
Designated Indication: *Treatment of diarrhea associated with vasoactive intestinal peptide tumors (VIPoma).*
Sponsor: Novartis Pharmaceuticals Corporation Date Designated: 8/24/1998
Address: 59 Route 10 Market Approval Date: 11/25/1998
East Hanover NJ 07936-1080

Generic Name: **Octreotide** Trade Name: **Sandostatin LAR**
Designated Indication: *Treatment of severe diarrhea and flushing associated with malignant carcinoid tumors.*
Sponsor: Novartis Pharmaceuticals Corporation Date Designated: 8/24/1998
Address: 59 Route 10 Market Approval Date: 11/25/1998
East Hanover NJ 07936-1080

Generic Name: **Ofloxacin** Trade Name: **Ocuflox Ophthalmic Solution**
Designated Indication: *Treatment of bacterial corneal ulcers.*
Sponsor: Allergan, Inc. Date Designated: 4/18/1991
Address: 2525 Dupont Drive Market Approval Date: 5/22/1996
P.O. Box 19534
Irvine CA 92713

Generic Name: **oglu fanide disodium** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of ovarian cancer*
Sponsor: Cytran, Inc. Date Designated: 9/24/2001
Address: 10230 NE Points Dr., NE Market Approval Date: Not currently Approved
Suite 530
Kirkland WA 98033-7869

Generic Name: **OM 401** Trade Name: **Drepanol**
Designated Indication: *Prophylactic treatment of sickle cell disease.*
Sponsor: Omex International, Inc. Date Designated: 10/24/1991
Address: 6001 Savoy, Suite 110 Market Approval Date: Not currently Approved
Houston TX 77036

Generic Name: **Omega-3 (n-3) polyunsaturated fatty acid with all double bonds in the cis configuration** Trade Name: **NONE ASSIGNED**
Designated Indication: *Prevention of organ graft rejection.*
Sponsor: Research Triangle Pharmaceuticals Date Designated: 11/22/1995
Address: 4364 South Alston Avenue Market Approval Date: Not currently Approved
Durham NC 27713

Generic Name: **Omega-3 (n-3) polyunsaturated fatty acids** Trade Name: **Omacor**
Designated Indication: *Treatment of IgA nephropathy.*
Sponsor: Pronova Biocare, AS Date Designated: 5/4/2000
Address: PO Box 420 Market Approval Date: Not currently Approved
1327 Lysaker
Norway

Generic Name: **Oncorad Ov103** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of ovarian cancer.*
Sponsor: Cytogen Corporation Date Designated: 4/24/1990
Address: 600 College Road East Market Approval Date: Not currently Approved
Princeton NJ 08540

Generic **Oprelvekin**
Name:

Trade **Neumega**
Name:

Designated *Prevention of severe chemotherapy-induced thrombocytopenia.*
Indication:

Sponsor: Genetics Institute, Inc.
Address: 87 Cambridge Park Drive
Cambridge MA 02140

Date Designated: 12/17/1996
Market Approval Date: 11/25/1997

Generic **Oxaliplatin**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of ovarian cancer.*
Indication:

Sponsor: Debio Pharm S.A.
Address: Rue des Terreaux 17
CH-1000
Lausanne 9 Switzerland CH

Date Designated: 10/6/1992
Market Approval Date: Not currently Approved

Generic **Oxandrolone**
Name:

Trade **Oxandrin**
Name:

Designated *Treatment of patients with Duchenne's muscular dystrophy and Becker's muscular dystrophy.*
Indication:

Sponsor: Bio-Technology General Corp.
Address: 70 Wood Avenue South
Iselin NJ 08830

Date Designated: 4/22/1997
Market Approval Date: Not currently Approved

Generic **Oxandrolone**
Name:

Trade **Oxandrin**
Name:

Designated *Adjunctive therapy for AIDS patients suffering from HIV-wasting syndrome.*
Indication:

Sponsor: Bio-Technology General Corp.
Address: 70 Wood Avenue, South
Iselin NJ 08830

Date Designated: 9/6/1991
Market Approval Date: Not currently Approved

Generic **Oxybate**
Name:

Trade **Xyrem**
Name:

Designated *Treatment of narcolepsy.*
Indication:

Sponsor: Orphan Medical, Inc.
Address: 13911 Ridgedale Drive
Suite 250
Minnetonka MN 55305

Date Designated: 11/7/1994
Market Approval Date: Not currently Approved

Generic Name: **Oxymorphone**

Trade Name: **Numorphan H.P.**

Designated Indication: *For relief of severe intractable pain in narcotic-tolerant patients.*

Sponsor: **DuPont Merck Pharmaceutical Company**
Address: **P.O. Box 80027
Wilmington DE 19880**

Date Designated: **3/19/1985**
Market Approval Date: **Not currently Approved**

Generic Name: **Oxypurinol**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of hyperuricemia in patients intolerant to allopurinol.*

Sponsor: **ILEX Oncology, Inc.**
Address: **4545 Horizon Hill Blvd.
San Antonio TX 78229-2263**

Date Designated: **11/9/1998**
Market Approval Date: **Not currently Approved**

Generic Name: **p1-(uridine 5'-)-p4-(2'-deoxycytidine 5'-) tetraphosphate, tetrasodium salt**

Trade Name: **NONE ASSIGNED**

Designated Indication: *For the treatment of cystic fibrosis*

Sponsor: **Inspire Pharmaceuticals, Inc.**
Address: **4222 Emperor Blvd.
Suite 470
Durham NC 27703**

Date Designated: **3/7/2001**
Market Approval Date: **Not currently Approved**

Generic Name: **Paclitaxel**

Trade Name: **Taxol**

Designated Indication: *Treatment of AIDS-related Kaposi's sarcoma.*

Sponsor: **Bristol-Myers Squibb Pharmaceutical**
Address: **5 Research Parkway
P.O. Box 5100
Wallingford CT 06492-7660**

Date Designated: **3/25/1997**
Market Approval Date: **8/4/1997**

Generic Name: **Paclitaxel**

Trade Name: **Paxene**

Designated Indication: *Treatment of AIDS-related Kaposi's sarcoma.*

Sponsor: **Baker Norton Pharmaceuticals, Inc.**
Address: **4400 Biscayne Boulevard
Miami FL 33137**

Date Designated: **4/15/1997**
Market Approval Date: **Not currently Approved**

Generic Name: **Papain, trypsin, and chymotrypsin**

Trade Name: **Wobe-Mugos**

Designated Indication: *Treatment of multiple myeloma.*

Sponsor: **Marlyn Nutraceuticals, Inc.**
Address: **14851 N. Scottsdale Rd.
Scottsdale AZ 85254**

Date Designated: **12/21/1998**
Market Approval Date: **Not currently Approved**

Generic Name: **Parovirus B19 (recombinant VP1 and VP2; S.frugiperda cells) vaccine**

Trade Name: **MEDI-491**

Designated Indication: *Prevention of transient aplastic crisis in patients with sickle cell anemia.*

Sponsor: **MedImmune, Inc.**
Address: **35 West Watkins Mill Rd.
Gaithersburg MD 20878**

Date Designated: **5/7/1999**
Market Approval Date: **Not currently Approved**

Generic Name: **Patul-end**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of patulous eustachian tube.*

Sponsor: **Ear Foundation**
Address: **2420 Castillo Street, Suite 100
Santa Barbara CA 93105**

Date Designated: **2/18/1997**
Market Approval Date: **Not currently Approved**

Generic Name: **PEG-glucocerebrosidase**

Trade Name: **Lysodase**

Designated Indication: *For use as chronic enzyme replacement therapy in patients with Gaucher's disease who are deficient in glucocerebrosidase.*

Sponsor: **National Institute of Mental Health, NIH**
Address: **49 Convent Dr. MSC4405
Bldg. 49, Room B1EE16
Bethesda MD 20892-4405**

Date Designated: **12/9/1992**
Market Approval Date: **Not currently Approved**

Generic Name: **PEG-interleukin-2**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of primary immunodeficiencies associated with T-cell defects.*

Sponsor: **Chiron Corporation**
Address: **4560 Horton Street
Emeryville CA 94608**

Date Designated: **2/1/1990**
Market Approval Date: **Not currently Approved**

Generic **Pegademase bovine** Trade Name: **Adagen**
Name:
Designated *For enzyme replacement therapy for ADA deficiency in patients with severe combined immunodeficiency.*
Indication:
Sponsor: **Enzon, Inc.** Date Designated: **5/29/1984**
Address: **20 Kingsbridge Road** Market Approval Date: **3/21/1990**
Piscataway NJ 08854

Generic **Pegaspargase** Trade Name: **Oncaspar**
Name:
Designated *Treatment of acute lymphocytic leukemia.*
Indication:
Sponsor: **Enzon, Inc.** Date Designated: **10/20/1989**
Address: **20 Kingsbridge Road** Market Approval Date: **2/1/1994**
Piscataway NJ 08854

Generic **Peginterferon alfa-2a** Trade Name: **PEGASYS**
Name:
Designated *Treatment of chronic myelogenous leukemia.*
Indication:
Sponsor: **Hoffman-La Roche Inc.** Date Designated: **9/30/1999**
Address: **340 Kingsland St.** Market Approval Date: **Not currently Approved**
Nutley NJ 07110-1199

Generic **Peginterferon alfa-2a** Trade Name: **PEGASYS**
Name:
Designated *Treatment of renal cell carcinoma.*
Indication:
Sponsor: **Hoffman-La Roche Inc.** Date Designated: **7/13/1998**
Address: **340 Kingsland St.** Market Approval Date: **Not currently Approved**
Nutley NJ 07110-1199

Generic **Pegvisomant** Trade Name: **Somavert**
Name:
Designated *Treatment of acromegaly.*
Indication:
Sponsor: **Sensus Corporation** Date Designated: **6/24/1997**
Address: **Suite 430,** Market Approval Date: **Not currently Approved**
98 San Jacinto Boulevard
Austin TX 78701

Generic Name: **Pegylated arginine deiminase** Trade Name: **Melanocid**
Designated Indication: *Treatment of invasive malignant melanoma.*
Sponsor: Phoenix Pharmacologics, Inc. Date Designated: 4/12/1999
Address: 115 John Robert Thomas Dr. Market Approval Date: Not currently Approved
Exton PA 19341

Generic Name: **Pegylated arginine deiminase** Trade Name: **Hepacid**
Designated Indication: *Treatment of hepatocellular carcinoma.*
Sponsor: Phoenix Pharmacologics, Inc. Date Designated: 3/26/1999
Address: 115 John Robert Thomas Dr. Market Approval Date: Not currently Approved
Exton PA 19341

Generic Name: **Pegylated recombinant human megakaryocyte growth and development factor** Trade Name: **MEGAGEN**
Designated Indication: *For reducing the period of thrombocytopenia in patients undergoing hematopoietic stem cell transplantation.*
Sponsor: Amgen, Inc. Date Designated: 10/20/1997
Address: One Amgen Center Dr. Market Approval Date: Not currently Approved
Thousand Oaks CA 91320-1789

Generic Name: **Peldesine** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of cutaneous T-cell lymphoma.*
Sponsor: BioCryst Pharmaceuticals, Inc. Date Designated: 10/5/1993
Address: 2190 Parkway Lake Drive Market Approval Date: Not currently Approved
Birmingham AL 35244

Generic Name: **pemetrexed disodium** Trade Name: **Alimta**
Designated Indication: *Treatment of malignant pleural mesothelioma*
Sponsor: Eli Lilly and Company Date Designated: 8/28/2001
Address: Lilly Corporate Center Market Approval Date: Not currently Approved
Indianapolis IN 46285

Generic **Pentamidine isethionate** Trade Name: **NONE ASSIGNED**
Name:
Designated *Treatment of Pneumocystis carinii pneumonia.*
Indication:
Sponsor: **Aventis Behring L.L.C.** Date Designated: **10/29/1984**
Address: **1020 First Avenue** Market Approval Date: **Not currently Approved**
PO Box 61501
King of Prussia PA 19406-0901

Generic **Pentamidine isethionate** Trade Name: **Nebupent**
Name:
Designated *Prevention of Pneumocystis carinii pneumonia in patients at high risk of developing this disease.*
Indication:
Sponsor: **Fujisawa USA, Inc.** Date Designated: **1/12/1988**
Address: **3 Parkway North Center** Market Approval Date: **6/15/1989**
Deerfield IL 60015

Generic **Pentamidine isethionate** Trade Name: **Pentam 300**
Name:
Designated *Treatment of Pneumocystis carinii pneumonia.*
Indication:
Sponsor: **Fujisawa USA, Inc.** Date Designated: **2/28/1984**
Address: **3 Parkway North Center** Market Approval Date: **10/16/1984**
Deerfield IL 60015

Generic **Pentamidine isethionate (inhalation)** Trade Name: **Pneumopent**
Name:
Designated *Prevention of Pneumocystis carinii pneumonia in patients at high risk of developing this disease.*
Indication:
Sponsor: **Fisons Corporation** Date Designated: **10/5/1987**
Address: **755 Jefferson Rd., P.O. Box 1710** Market Approval Date: **Not currently Approved**
Rochester NY 14603

Generic **Pentastarch** Trade Name: **Pentaspan**
Name:
Designated *As an adjunct in leukapheresis to improve the harvesting and increase the yield of leukocytes by centrifugal means.*
Indication:
Sponsor: **Du Pont Pharmaceuticals** Date Designated: **8/28/1985**
Address: **E.I. Du Pont De Nemours & Co.** Market Approval Date: **5/19/1987**
Wilmington DE 19898

Generic **Pentosan polysulfate sodium**
Name:

Trade **Elmiron**
Name:

Designated *Treatment of interstitial cystitis.*
Indication:

Sponsor: **Alza Corporation**
Address: **950 Page Mill Rd.
PO Box 10950
Palo Alto CA 94303-0802**

Date Designated: **8/7/1985**
Market Approval Date: **9/26/1996**

Generic **Pentostatin**
Name:

Trade **Nipent**
Name:

Designated *Treatment of peripheral T-cell lymphomas.*
Indication:

Sponsor: **SuperGen, Inc.**
Address: **4140 Dublin Blvd.
Suite 200
Dublin CA 94568**

Date Designated: **11/24/1999**
Market Approval Date: **Not currently Approved**

Generic **Pentostatin**
Name:

Trade **Nipent**
Name:

Designated *Treatment of cutaneous T-cell lymphoma.*
Indication:

Sponsor: **SuperGen, Inc.**
Address: **4140 Dublin Blvd.
Suite 200
Dublin CA 94568**

Date Designated: **3/27/1998**
Market Approval Date: **Not currently Approved**

Generic **Pentostatin**
Name:

Trade **Nipent**
Name:

Designated *Treatment of patients with chronic lymphocytic leukemia.*
Indication:

Sponsor: **SuperGen, Inc.**
Address: **4140 Dublin Blvd.
Suite 200
Dublin CA 94568**

Date Designated: **1/29/1991**
Market Approval Date: **Not currently Approved**

Generic **Pentostatin for injection**
Name:

Trade **Nipent**
Name:

Designated *Treatment of hairy cell leukemia.*
Indication:

Sponsor: **SuperGen, Inc.**
Address: **4140 Dublin Blvd.
Suite 200
Dublin CA 94568**

Date Designated: **9/10/1987**
Market Approval Date: **10/11/1991**

Generic **Perflubron** Trade Name: **LiquiVent**
Name:
Designated *Treatment of acute respiratory distress disease (ARDS) in adults*
Indication:
Sponsor: Alliance Pharmaceutical Corp. Date Designated: 4/26/2001
Address: 3040 Science Park Road Market Approval Date: Not currently Approved
San Diego CA 92191

Generic **Pergolide** Trade Name: **Permax**
Name:
Designated *Treatment of Tourette's syndrome.*
Indication:
Sponsor: Sallee, Floyd R. M.D., Ph.D. Date Designated: 11/20/1997
Address: Medical University of South Carolina Market Approval Date: Not currently Approved
171 Ashley Avenue, Room PH246
Charleston SC 29425

Generic **Phenylacetate** Trade Name: **NONE ASSIGNED**
Name:
Designated *For use as an adjunct to surgery, radiation therapy and chemotherapy for the treatment of patients with primary*
Indication: *or recurrent malignant glioma.*
Sponsor: Elan Pharmaceutical Research Corp. Date Designated: 3/6/1998
Address: 1300 Gould Dr. Market Approval Date: Not currently Approved
Gainesville GA 30504

Generic **Phenylalanine ammonia-lyase** Trade Name: **Phenylase**
Name:
Designated *Treatment of hyperphenylalaninemia.*
Indication:
Sponsor: Ibex Technologies, Inc. Date Designated: 3/8/1995
Address: 5485 Pare Market Approval Date: Not currently Approved
Montreal, Quebec
Canada H4P 1P7 CA

Generic **Phenylbutyrate** Trade Name: **NONE ASSIGNED**
Name:
Designated *Treatment of acute promyelocytic leukemia.*
Indication:
Sponsor: Elan Corporation Date Designated: 1/19/2000
Address: 1300 Gould Dr. Market Approval Date: Not currently Approved
Gainesville GA 30504

Generic Name: **Phosphocysteamine**

Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of cystinosis.*

Sponsor: Medea Research Laboratories
Address: Port Jefferson Business Center
200 Wilson Street, Building D-6
Port Jefferson NY 11776

Date Designated: 9/12/1988
Market Approval Date: Not currently Approved

Generic Name: **physostigmine salicylate**

Trade Name: Antilirium

Designated Indication: *Treatment of Friedreich's and other inherited ataxias.*

Sponsor: Forest Pharmaceuticals, Inc.
Address: 150 East 58th Street
New York NY 10155

Date Designated: 1/16/1985
Market Approval Date: Not currently Approved

Generic Name: **Pilocarpine**

Trade Name: Salagen

Designated Indication: *Treatment of xerostomia induced by radiation therapy for head and neck cancer.*

Sponsor: MGI Pharma, Inc.
Address: 6300 West Old Shakopee Rd.
Suite 110
Bloomington MN 55438-2318

Date Designated: 9/24/1990
Market Approval Date: 3/22/1994

Generic Name: **Pilocarpine HCl**

Trade Name: Salagen

Designated Indication: *Treatment of xerostomia and keratoconjunctivitis sicca in Sjogren's syndrome patients.*

Sponsor: MGI Pharma, Inc.
Address: 6300 West Old Shakopee Rd.
Suite 110
Bloomington MN 55438-2318

Date Designated: 2/28/1992
Market Approval Date: 2/11/1998

Generic Name: **Piracetam**

Trade Name: Nootropil

Designated Indication: *Treatment of myoclonus.*

Sponsor: UCB Pharma, Inc.
Address: 1950 Lake Park Drive
Smyrna GA 30080

Date Designated: 10/2/1987
Market Approval Date: Not currently Approved

Generic Name: **Polifeprosan 20 with carmustine**

Trade Name: Gliadel

Designated Indication: *Treatment of malignant glioma.*

Sponsor: Guilford Pharmaceuticals, Inc.
Address: 6611 Tributary Street
Baltimore MD 21224

Date Designated: 12/13/1989
Market Approval Date: 9/23/1996

Generic Name: **Poloxamer 188**

Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of vasospasm in subarachnoid hemorrhage patients following surgical repair of a ruptured cerebral aneurysm.*

Sponsor: CytRx Corporation
Address: 154 Technology Parkway
Norcross GA 30092

Date Designated: 8/5/1997
Market Approval Date: Not currently Approved

Generic Name: **Poloxamer 188**

Trade Name: Flocor

Designated Indication: *Treatment of sickle cell crisis.*

Sponsor: CytRx Corporation
Address: 154 Technology Parkway
Norcross GA 30092

Date Designated: 6/27/1989
Market Approval Date: Not currently Approved

Generic Name: **Poloxamer 188**

Trade Name: Florcor

Designated Indication: *Treatment of severe burns requiring hospitalization.*

Sponsor: CytRx Corporation
Address: 154 Technology Parkway
Norcross GA 30092

Date Designated: 2/22/1990
Market Approval Date: Not currently Approved

Generic Name: **Poloxamer 331**

Trade Name: Protox

Designated Indication: *Initial therapy of toxoplasmosis in patients with AIDS.*

Sponsor: CytRx Corporation
Address: 154 Technology Parkway
Norcross GA 30092

Date Designated: 3/21/1991
Market Approval Date: Not currently Approved

Generic **Poly I: poly C12U**
Name:

Trade Name: Ampligen

Designated *Treatment of AIDS.*
Indication:

Sponsor: Hemispherx Biopharma, Inc.
Address: One Penn Center
1617 JFK Boulevard
Philadelphia PA 19103

Date Designated: 7/19/1988
Market Approval Date: Not currently Approved

Generic **Poly I: poly C12U**
Name:

Trade Name: Ampligen

Designated *Treatment of chronic fatigue syndrome.*
Indication:

Sponsor: Hemispherx Biopharma, Inc.
Address: One Penn Center
1617 JFK Boulevard
Philadelphia PA 19103

Date Designated: 12/9/1993
Market Approval Date: Not currently Approved

Generic **Poly I: poly C12U**
Name:

Trade Name: Ampligen

Designated *Treatment of invasive metastatic melanoma (stage IIb, III, IV).*
Indication:

Sponsor: Hemispherx Biopharma, Inc.
Address: One Penn Center
1617 JFK Boulevard
Philadelphia PA 19103

Date Designated: 12/9/1993
Market Approval Date: Not currently Approved

Generic **Poly I: poly C12U**
Name:

Trade Name: Ampligen

Designated *Treatment of renal cell carcinoma.*
Indication:

Sponsor: Hemispherx Biopharma, Inc.
Address: One Penn Center
1617 JFK Boulevard
Philadelphia PA 19103

Date Designated: 5/20/1991
Market Approval Date: Not currently Approved

Generic **Poly-ICLC**
Name:

Trade Name: NONE ASSIGNED

Designated *Treatment of primary brain tumors.*
Indication:

Sponsor: Salazar, Andres M. M.D. and Levy, Hilton B.
Address: 3202 Cleveland Avenue N.W.
Washington DC 20008

Date Designated: 3/17/1997
Market Approval Date: Not currently Approved

Generic Name: **Polyethylene glycol (PEG)-uricase**

Trade Name: **NONE ASSIGNED**

Designated Indication: *To control the clinical consequences of hyperuricemia in patients with severe gout in whom conventional therapy is contraindicated or has been ineffective.*

Sponsor: **Bio-Technology General Corporation**
Address: **70 Wood Avenue South
Iselin NJ 08830**

Date Designated: **2/21/2001**
Market Approval Date: **Not currently Approved**

Generic Name: **Polyethylene glycol-modified uricase**

Trade Name: **Zurase**

Designated Indication: *Prophylaxis of hyperuricemia in cancer patients prone to develop tumor lysis syndrome during chemotherapy.*

Sponsor: **Phoenix Pharmacologics, Inc.**
Address: **115 John Robert Thomas Dr.
Exton PA 19341**

Date Designated: **9/14/1999**
Market Approval Date: **Not currently Approved**

Generic Name: **Polyethylene glycol-modified uricase**

Trade Name: **Zurase**

Designated Indication: *Treatment of tumor lysis syndrome in cancer patients undergoing chemotherapy.*

Sponsor: **Phoenix Pharmacologics, Inc.**
Address: **115 John Robert Thomas Dr.
Exton PA 19341**

Date Designated: **12/21/1998**
Market Approval Date: **Not currently Approved**

Generic Name: **Polymeric oxygen**

Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of sickle cell anemia.*

Sponsor: **Capmed USA**
Address: **P.O. Box 14
Bryn Mawr PA 19010**

Date Designated: **3/25/1992**
Market Approval Date: **Not currently Approved**

Generic Name: **Porcine fetal neural dopaminergic cells and/or precursors aseptically prepared and coated with anti-MHC-1 Ab for intracerebral implantation**

Trade Name: **NeuroCell-PD**

Designated Indication: *Treatment of Hoehn and Yahr stage 4 and 5 Parkinson's disease.*

Sponsor: **Diacrin, Inc.**
Address: **One Kendall Square
Cambridge MA 02139-1562**

Date Designated: **12/17/1996**
Market Approval Date: **Not currently Approved**

Generic Name: **Porcine fetal neural dopaminergic cells and/or precursors aseptically prepared for intracerebral** Trade Name: **NeuroCell-PD**
Designated Indication: *Treatment of Hoehn and Yahr stage 4 and 5 Parkinson's disease.*
Sponsor: **Diacrin, Inc.** Date Designated: **12/17/1996**
Address: **One Kendall Square** Market Approval Date: **Not currently Approved**
Cambridge MA 02139-1562

Generic Name: **Porcine fetal neural gabaergic cells and/or precursors aseptically prepared and coated with anti-MHC-1 Ab for intracerebral implantation** Trade Name: **NeuroCell-HD**
Designated Indication: *Treatment of Huntington's disease.*
Sponsor: **Diacrin, Inc.** Date Designated: **12/10/1996**
Address: **One Kendall Square** Market Approval Date: **Not currently Approved**
Cambridge MA 02129-1562

Generic Name: **Porcine fetal neural gabaergic cells and/or precursors aseptically prepared for intracerebral implantation for Huntington's disease.** Trade Name: **NeuroCell-HD**
Designated Indication: *Treatment of Huntington's disease.*
Sponsor: **Diacrin, Inc.** Date Designated: **12/10/1996**
Address: **One Kendall Square** Market Approval Date: **Not currently Approved**
Cambridge MA 02139-1562

Generic Name: **Porcine Sertoli cells aseptically prepared for intracerebral co-implantation with fetal neural tissue** Trade Name: **N-Graft**
Designated Indication: *Treatment of Hoehn and Yahr stage four and five Parkinson's disease.*
Sponsor: **Titan Pharmaceuticals, Inc.** Date Designated: **6/24/1997**
Address: **Post Office Plaza** Market Approval Date: **Not currently Approved**
50 Division Street, Suite 503
Somerville NJ 08876

Generic Name: **porfimer** Trade Name: **Photofrin**
Designated Indication: *For the ablation of High-Grade Dysplasia in Barrett's Esophagus in patients who are not considered to be candidates for esophagectomy*
Sponsor: **Axcan Scandipharm Inc.** Date Designated: **10/19/2001**
Address: **22 Inverness Parkway** Market Approval Date: **Not currently Approved**
Suite 310
Birmingham AL 35242

Generic **Porfimer sodium** Trade **Photofrin**
Name: Name:
Designated *For the photodynamic therapy of patients with transitional cell carcinoma in situ of the urinary bladder.*
Indication:
Sponsor: QLT Phototherapeutics, Inc. Date Designated: 11/15/1989
Address: Lederle Laboratories Market Approval Date: Not currently Approved
401 North Middletown Road
Pearl River NY 10965

Generic **Porfimer sodium** Trade **Photofrin**
Name: Name:
Designated *For the photodynamic therapy of patients with primary or recurrent obstructing (either partially or completely)*
Indication: *esophageal carcinoma.*
Sponsor: QLT Phototherapeutics, Inc. Date Designated: 6/6/1989
Address: Lederle Laboratories Market Approval Date: 12/27/1995
401 North Middletown Road
Pearl River NY 10965

Generic **Porfiromycin** Trade **Promycin**
Name: Name:
Designated *Treatment of head and neck cancer.*
Indication:
Sponsor: Boehringer Ingelheim Pharmaceuticals, Inc. Date Designated: 9/19/1995
Address: 900 Ridgebury Road Market Approval Date: Not currently Approved
PO Box 368
Ridgefield CT 06877

Generic **Porfiromycin** Trade **Promycin**
Name: Name:
Designated *Treatment of cervical cancer.*
Indication:
Sponsor: Boehringer Ingelheim Pharmaceuticals, Inc. Date Designated: 3/13/1997
Address: 900 Ridgebury Road Market Approval Date: Not currently Approved
PO Box 368
Ridgefield CT 06877

Generic **Potassium citrate** Trade **Urocit-K**
Name: Name:
Designated *For avoidance of the complication of calcium stone formation in patients with uric lithiasis.*
Indication:
Sponsor: University of Texas Health Science Center at Date Designated: 9/12/1985
Address: 5323 Harry Hines Blvd Market Approval Date: 8/30/1985
Dallas TX 75235

Generic Name: **Potassium citrate** Trade Name: **Urocit-K**
Designated Indication: *Prevention of uric acid nephrolithiasis.*
Sponsor: University of Texas Health Science Center at Date Designated: 11/1/1984
Address: 5323 Harry Hines Boulevard Market Approval Date: 8/30/1985
Dallas TX 75235

Generic Name: **Potassium citrate** Trade Name: **Urocit-K**
Designated Indication: *Prevention of calcium renal stones in patients with hypocitraturia.*
Sponsor: University of Texas Health Science Center at Date Designated: 9/16/1985
Address: 5323 Harry Hines Blvd Market Approval Date: 8/30/1985
Dallas TX 75235

Generic Name: **Primaquine phosphate** Trade Name: **NONE ASSIGNED**
Designated Indication: *For use in combination with clindamycin hydrochloride in the treatment of Pneumocystis carinii pneumonia associated with AIDS.*
Sponsor: Sanofi Winthrop, Inc. Date Designated: 7/23/1993
Address: 90 Park Avenue Market Approval Date: Not currently Approved
New York NY 10016

Generic Name: **Progesterone** Trade Name: **NONE ASSIGNED**
Designated Indication: *Establishment and maintenance of pregnancy in women undergoing in vitro fertilization or embryo transfer procedures.*
Sponsor: Watson Laboratories, Inc. Date Designated: 12/22/1994
Address: 311 Bonnie Circle Market Approval Date: Not currently Approved
Corona CA 91720

Generic Name: **Prostaglandin E1 enol ester (AS-013)** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of Fontaine Stage IV chronic critical limb ischemia.*
Sponsor: Welfide International Corporation Date Designated: 6/12/1998
Address: 5555 Valley Boulevard Market Approval Date: Not currently Approved
Los Angeles CA 90032

Generic Name: **Protein C concentrate** Trade Name: Protein C Concentrate (human) Vapor Heated, Immuno
Designated Indication: *For replacement therapy in congenital protein C deficiency for the prevention and treatment of thrombosis, pulmonary emboli, and purpura fulminans.*
Sponsor: Baxter Healthcare Corporation Date Designated: 6/23/1992
Address: Hyland Division (Baxter Hyland) Market Approval Date: Not currently Approved
550 North Brand Blvd.
Glendale CA 91203

Generic Name: **Protein C concentrate** Trade Name: Protein C Concentrate (human) Vapor Heated, Immuno
Designated Indication: *For replacement therapy in patients with congenital or acquired protein C deficiency for the prevention and treatment of warfarin-induced skin necrosis during oral anticoagulation.*
Sponsor: Immuno Clinical Research Corp. Date Designated: 6/19/1992
Address: 750 Lexington Avenue, 19th Floor Market Approval Date: Not currently Approved
New York NY 10022

Generic Name: **Pulmonary surfactant replacement, porcine** Trade Name: Curosurf
Designated Indication: *For the treatment and prevention of respiratory distress syndrome in premature infants.*
Sponsor: Dey Laboratories Date Designated: 8/2/1993
Address: 2751 Napa Valley Corporate Drive Market Approval Date: Not currently Approved
Napa CA 94558

Generic Name: **Purified extract of Pseudomonas aeruginosa** Trade Name: ImmuDyn
Designated Indication: *Treatment of immune thrombocytopenia purpura where it is required to increase platelet counts.*
Sponsor: DynaGen, Inc. Date Designated: 9/22/1997
Address: 99 Erie Street Market Approval Date: Not currently Approved
Cambridge MA 02139

Generic Name: **Purified type II collagen** Trade Name: Colloral
Designated Indication: *Treatment of juvenile rheumatoid arthritis.*
Sponsor: AutoImmune, Inc. Date Designated: 2/9/1995
Address: 128 Spring Street Market Approval Date: Not currently Approved
Lexington MA 02421

Generic Name: **pVGL1(VEGF2)** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of thromboangiitis obliterans.*
Sponsor: Vascular Genetics, Inc. Date Designated: 11/9/1999
Address: 200 Westpark Corporate Center Market Approval Date: Not currently Approved
4364 South Alston Ave.
Durham NC 27713-2280

Generic Name: **Pyruvate** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of interstitial lung disease.*
Sponsor: Cellular Sciences, Inc. Date Designated: 2/21/2001
Address: 84 park Avenue Market Approval Date: Not currently Approved
P.O. Box 968
Flemington NJ 08822

Generic Name: **Radiolabeled monoclonal antibody to CD22 antigen on B-cells** Trade Name: **LymphoCIDE**
Designated Indication: *Treatment of non-Hodgkin's lymphoma.*
Sponsor: Immunomedics, Inc. Date Designated: 7/13/1998
Address: 300 American Rd. Market Approval Date: Not currently Approved
Morris Plains NJ 07950

Generic Name: **Recombinant bactericidal/permeability-increasing protein** Trade Name: **Neuprex**
Designated Indication: *Treatment of severe meningococcal disease.*
Sponsor: Xoma Corporation Date Designated: 6/22/1998
Address: 2910 Seventh Street Market Approval Date: Not currently Approved
Berkeley CA 94710

Generic Name: **Recombinant glycine2-human glucagon-like peptide-2** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of short bowel syndrome.*
Sponsor: NPS Allelix Corp. Date Designated: 6/29/2000
Address: 6850 Goreway Dr. Market Approval Date: Not currently Approved
Mississauga, Ontario
L4V 1V7 Canada CA

Generic Name: **Recombinant human acid alpha-glucosidase** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of glycogen storage disease type II.*
Sponsor: Genzyme Corporation Date Designated: 8/19/1997
Address: 15 Pleasant Street Market Approval Date: Not currently Approved
P.O. Box 9322
Framingham MA 01701-9322

Generic Name: **recombinant human alpha 1-antitrypsin (rAAT)** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of cystic fibrosis*
Sponsor: Arriva Pharmaceuticals, Inc. Date Designated: 11/20/2001
Address: 2020 Challenger Drive Market Approval Date: Not currently Approved
Alameda CA 94501

Generic Name: **recombinant human alpha-1 antitrypsin** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of cystic fibrosis.*
Sponsor: PPL Therapeutics (Scotland) Limited Date Designated: 3/6/1998
Address: Roslin, Edinburgh Market Approval Date: Not currently Approved
EH25 9PP Scotland GB

Generic Name: **recombinant human alpha-1 antitrypsin (rAAT)** Trade Name: **NONE ASSIGNED**
Designated Indication: *To delay progression of chronic obstructive pulmonary disease resulting from AAT deficiency-mediated emphysema and bronchiectasis*
Sponsor: Baxter Healthcare Corporation Date Designated: 8/28/2001
Address: 550 N. Brand Blvd. Market Approval Date: Not currently Approved
Glendale CA 91203

Generic Name: **Recombinant Human Alpha-Fetoprotein (rhAFP)** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of myasthenia gravis*
Sponsor: Atlantic Biopharmaceuticals, Inc. Date Designated: 2/22/2001
Address: 50 Church Street Market Approval Date: Not currently Approved
5th floor
Cambridge MA 02138

Generic Name: **Recombinant human antithrombin III** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of antithrombin III dependent heparin resistance requiring anticoagulation.*
Sponsor: **AT III LLC** Date Designated: **4/6/2000**
Address: **c/o Genzyme Corporation** Market Approval Date: **Not currently Approved**
15 Pleasant St. Connector, P.O. Box 9322
Framingham MA 01701

Generic Name: **Recombinant human C1-esterase inhibitor** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of (acute attacks of) angioedema caused by hereditary or acquired C1-esterase inhibitor deficiency.*
Sponsor: **Pharming N.V.** Date Designated: **2/23/1999**
Address: **Cipalstreet 3** Market Approval Date: **Not currently Approved**
B-2440 Geel
Belgium BE

Generic Name: **Recombinant human C1-esterase inhibitor** Trade Name: **NONE ASSIGNED**
Designated Indication: *Prophylactic treatment of angioedema caused by hereditary or acquired C1-esterase inhibitor deficiency.*
Sponsor: **Pharming N.V.** Date Designated: **2/23/1999**
Address: **Cipalstreet 3** Market Approval Date: **Not currently Approved**
B-2440 Geel
Belgium BE

Generic Name: **Recombinant human CD4 immunoglobulin G** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of AIDS resulting from infection with HIV-1.*
Sponsor: **Genentech, Inc.** Date Designated: **8/30/1990**
Address: **460 Point San Bruno Boulevard** Market Approval Date: **Not currently Approved**
South San Francisco CA 94080

Generic Name: **Recombinant human Clara Cell 10kDa protein** Trade Name: **NONE ASSIGNED**
Designated Indication: *Prevention of neonatal bronchopulmonary dysplasia in premature neonates with respiratory distress syndrome.*
Sponsor: **Clragen, Inc.** Date Designated: **7/13/1998**
Address: **335 Paint Branch Drive** Market Approval Date: **Not currently Approved**
College Park MD 20742

Generic Name: **recombinant human endostatin protein** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of neuroendocrine tumors.*
Sponsor: **EntreMed, Inc.** Date Designated: **8/13/2001**
Address: **9640 Medical Center Drive** Market Approval Date: **Not currently Approved**
Rockville MD 20850

Generic Name: **Recombinant human gelsolin** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of the respiratory symptoms of cystic fibrosis.*
Sponsor: **Biogen, Inc.** Date Designated: **1/12/1994**
Address: **14 Cambridge Center** Market Approval Date: **Not currently Approved**
Cambridge MA 02124

Generic Name: **Recombinant human gelsolin** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of acute and chronic respiratory symptoms of bronchiectasis.*
Sponsor: **Biogen, Inc.** Date Designated: **3/6/1995**
Address: **14 Cambridge Center** Market Approval Date: **Not currently Approved**
Cambridge MA 02142

Generic Name: **Recombinant human highly phosphorylated acid alpha-glucosidase** Trade Name: **TBD**
Designated Indication: *For enzyme replacement therapy in patients with all subtypes of glycogen storage disease type II (GSDII, Pompe Disease)*
Sponsor: **Novazyme Pharmaceuticals, Inc.** Date Designated: **9/20/2000**
Address: **800 Research Parkway** Market Approval Date: **Not currently Approved**
Suite 200
Oklahoma City OK 73104

Generic Name: **Recombinant human insulin-like growth factor-I** Trade Name: **PV802**
Designated Indication: *Treatment of short-bowel syndrome as a result of resection of the small bowel or as a result of congenital dysfunction of the intestines.*
Sponsor: **GroPep Pty Ltd.** Date Designated: **2/16/2000**
Address: **Gate 11, Victoria Dr.** Market Approval Date: **Not currently Approved**
Adelaide SA 5000
Australia AU

Generic Name: **Recombinant human insulin-like growth factor-I** Trade Name: NONE ASSIGNED
Designated Indication: *Treatment of post-poliomyelitis syndrome.*
Sponsor: Cephalon, Inc. Date Designated: 10/13/1995
Address: 145 Brandywine Parkway Market Approval Date: Not currently Approved
West Chester PA 19380-4245

Generic Name: **Recombinant human insulin-like growth factor-I/insulin-like growth factor binding protein-3** Trade Name: NONE ASSIGNED
Designated Indication: *Treatment of major burns that require hospitalization.*
Sponsor: Celtrix Pharmaceuticals, Inc. Date Designated: 6/15/1999
Address: 3055 Patrick Henry Dr. Market Approval Date: Not currently Approved
Santa Clara CA 95054

Generic Name: **Recombinant human interleukin-12** Trade Name: NONE ASSIGNED
Designated Indication: *Treatment of renal cell carcinoma.*
Sponsor: Genetics Institute, Inc. Date Designated: 10/20/1997
Address: 87 CambridgePark Drive Market Approval Date: Not currently Approved
Cambridge MA 02140

Generic Name: **Recombinant human keratinocyte growth factor** Trade Name: NONE ASSIGNED
Designated Indication: *Reducing the incidence and severity of radiation-induced xerostomia.*
Sponsor: Amgen Inc. Date Designated: 12/20/1999
Address: One Amgen Center Dr. Market Approval Date: Not currently Approved
Thousand Oaks CA 91320-1799

Generic Name: **Recombinant human luteinizing hormone** Trade Name: LHadi
Designated Indication: *For use in association with recombinant human follicle stimulating hormone for the treatment of women with chronic anovulation due to hypogonadotropic hypogonadism.*
Sponsor: Serono Laboratories, Inc. Date Designated: 10/7/1994
Address: 100 Longwater Circle Market Approval Date: Not currently Approved
Norwell MA 02061

Generic Name: **Recombinant human nerve growth factor**

Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of HIV-associated sensory neuropathy.*

Sponsor: Genentech, Inc.
Address: 1 DNA Way
South San Francisco CA 94080

Date Designated: 4/16/1999
Market Approval Date: Not currently Approved

Generic Name: **Recombinant human relaxin**

Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of progressive systemic sclerosis.*

Sponsor: Connetics Corporation
Address: 3400 West Bayshore Road
Palo Alto CA 94303

Date Designated: 11/3/1995
Market Approval Date: Not currently Approved

Generic Name: **Recombinant human superoxide dismutase**

Trade Name: Oxsodrol

Designated Indication: *Prevention of bronchopulmonary dysplasia in premature neonates weighing less than 1500 grams.*

Sponsor: Bio-Technology General Corp.
Address: 70 Wood Avenue, South
Iselin NJ 08830

Date Designated: 4/18/1991
Market Approval Date: Not currently Approved

Generic Name: **Recombinant human thrombopoietin**

Trade Name: NONE ASSIGNED

Designated Indication: *For use in accelerating platelet recovery in patients undergoing hematopoietic stem cell transplantation.*

Sponsor: Genentech, Inc.
Address: 1 DNA Way
South San Francisco CA 94080-4990

Date Designated: 9/29/1997
Market Approval Date: Not currently Approved

Generic Name: **Recombinant humanized MAb 5c8**

Trade Name: NONE ASSIGNED

Designated Indication: *Prevention of rejection of pancreatic islet cell transplants.*

Sponsor: Biogen, Inc.
Address: 14 Cambridge Center
Cambridge MA 02142

Date Designated: 3/22/1999
Market Approval Date: Not currently Approved

Generic Name: **Recombinant humanized MAb 5c8** Trade Name: **NONE ASSIGNED**
Designated Indication: *Prevention and treatment of Factor VIII/Factor IX inhibitors in patients with hemophilia A or B.*
Sponsor: **Biogen, Inc.** Date Designated: **10/14/1998**
Address: **14 Cambridge Center** Market Approval Date: **Not currently Approved**
Cambridge MA 02142

Generic Name: **Recombinant humanized MAb 5c8** Trade Name: **NONE ASSIGNED**
Designated Indication: *Prevention of rejection of solid organ transplants.*
Sponsor: **Biogen, Inc.** Date Designated: **3/22/1999**
Address: **14 Cambridge Center** Market Approval Date: **Not currently Approved**
Cambridge MA 02142

Generic Name: **Recombinant humanized monoclonal antibody 5c8** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of immune thrombocytopenic purpura.*
Sponsor: **Biogen, Inc.** Date Designated: **2/3/1998**
Address: **14 Cambridge Center** Market Approval Date: **Not currently Approved**
Cambridge MA 02142

Generic Name: **Recombinant humanized monoclonal antibody 5c8** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of systemic lupus erythematosus.*
Sponsor: **Biogen, Inc.** Date Designated: **2/18/1998**
Address: **14 Cambridge Center** Market Approval Date: **Not currently Approved**
Cambridge MA 02142

Generic Name: **Recombinant methionyl brain-derived neurotrophic factor** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of amyotrophic lateral sclerosis.*
Sponsor: **Amgen, Inc.** Date Designated: **11/28/1994**
Address: **One Amgen Center Dr.** Market Approval Date: **Not currently Approved**
Thousand Oaks CA 91320-1799

Generic Name: **Recombinant methionyl human stem cell factor** Trade Name: NONE ASSIGNED
Designated Indication: *Treatment of primary bone marrow failure.*
Sponsor: Amgen, Inc. Date Designated: 11/22/1995
Address: One Amgen Center Drive Market Approval Date: Not currently Approved
Thousand Oaks CA 91320-1799

Generic Name: **Recombinant retroviral vector - glucocerebrosidase** Trade Name: NONE ASSIGNED
Designated Indication: *For use as enzyme replacement therapy for patients with types I, II, or III Gaucher disease.*
Sponsor: Genetic Therapy, Inc. Date Designated: 11/15/1993
Address: 938 Clopper Road Market Approval Date: Not currently Approved
Gaithersburg MD 20878

Generic Name: **Recombinant secretory leucocyte protease inhibitor** Trade Name: NONE ASSIGNED
Designated Indication: *Treatment of cystic fibrosis.*
Sponsor: Amgen, Inc. Date Designated: 3/29/1991
Address: 3200 Walnut Street Market Approval Date: Not currently Approved
Boulder CO 80301

Generic Name: **Recombinant secretory leucocyte protease inhibitor** Trade Name: NONE ASSIGNED
Designated Indication: *Treatment of congenital alpha-1 antitrypsin deficiency.*
Sponsor: Amgen Inc. Date Designated: 3/29/1991
Address: 3200 Walnut Street Market Approval Date: Not currently Approved
Boulder CO 80301

Generic Name: **Recombinant soluble human CD4 (rCD4)** Trade Name: NONE ASSIGNED
Designated Indication: *Treatment of AIDS in patients infected with HIV virus.*
Sponsor: Genentech, Inc. Date Designated: 3/23/1989
Address: 460 Point San Bruno Boulevard Market Approval Date: Not currently Approved
South San Francisco CA 94080

Generic Name: **Recombinant urate oxidase** Trade Name: **NONE ASSIGNED**
Designated Indication: *Prophylaxis of chemotherapy-induced hyperuricemia.*
Sponsor: **Sanofi-Synthelabo Research** Date Designated: **10/11/2000**
Address: **9 Great Valley Parkway** Market Approval Date: **Not currently Approved**
Malvern PA 19355

Generic Name: **Recombinant urate oxidase** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of malignancy-associated or chemotherapy-induced hyperuricemia.*
Sponsor: **Sanofi-Synthelabo Research** Date Designated: **10/11/2000**
Address: **9 Great Valley Parkway** Market Approval Date: **Not currently Approved**
Malvern PA 19355

Generic Name: **Recombinant vaccinia (human papillomavirus)** Trade Name: **TA-HPV**
Designated Indication: *Treatment of cervical cancer.*
Sponsor: **Cantab Pharmaceuticals Research Limited** Date Designated: **8/24/1994**
Address: **310 Cambridge Science Park** Market Approval Date: **Not currently Approved**
Cambridge CB4 0WG
Great Britain GB

Generic Name: **Reduced L-glutathione** Trade Name: **Cachexon**
Designated Indication: *Treatment of AIDS-associated cachexia.*
Sponsor: **Telluride Pharmaceutical Corporation** Date Designated: **2/14/1994**
Address: **146 Flanders Drive** Market Approval Date: **Not currently Approved**
Hillsborough NJ 08876

Generic Name: **Remacemide** Trade Name: **Ecovia**
Designated Indication: *Treatment of Huntington's disease.*
Sponsor: **AstraZeneca LP** Date Designated: **3/6/2000**
Address: **725 Chesterbrook Blvd.** Market Approval Date: **Not currently Approved**
Wayne PA 19087-5677

Generic Name: **Respiratory Syncytial Virus Immune Globulin (human)** Trade Name: **Hypermune RSV**
Designated Indication: *Treatment of respiratory syncytial virus lower respiratory tract infections in hospitalized infants and young children.*
Sponsor: **MedImmune, Inc.** Date Designated: **9/27/1990**
Address: **35 West Watkins Mill Road** Market Approval Date: **Not currently Approved**
Gaithersburg MD 20878

Generic Name: **Respiratory syncytial virus immune globulin (Human)** Trade Name: **Respigam**
Designated Indication: *Prophylaxis of respiratory syncytial virus lower respiratory tract infections in infants and young children at high risk of RSV disease.*
Sponsor: **MedImmune & Massachusetts Public Health** Date Designated: **9/27/1990**
Address: **35 West Watkins Mill Road** Market Approval Date: **1/18/1996**
Gaithersburg MD 20878

Generic Name: **Retroviral vector, R-GC and GC gene 1750** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of Gaucher disease.*
Sponsor: **Genzyme Corporation** Date Designated: **5/6/1997**
Address: **One Mountain Road** Market Approval Date: **Not currently Approved**
P.O. Box 9322
Framingham MA 01701-9322

Generic Name: **Reviparin sodium** Trade Name: **Clivarine**
Designated Indication: *Treatment of deep vein thrombosis which may lead to pulmonary embolism in pediatric patients*
Sponsor: **Knoll AG** Date Designated: **6/18/2001**
Address: **Ludwigshafen, Germany** Market Approval Date: **Not currently Approved**

Generic Name: **Reviparin sodium** Trade Name: **Clivarine**
Designated Indication: *Long-term treatment of acute deep vein thrombosis with or without pulmonary embolism in pregnant patients*
Sponsor: **Knoll AG** Date Designated: **6/18/2001**
Address: **Ludwigshafen, Germany** Market Approval Date: **Not currently Approved**

Generic Name: **RGG0853, E1A lipid complex** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of ovarian cancer.*
Sponsor: Targeted Genetics Corporation Date Designated: 9/15/1995
Address: 1100 Olive Way, Suite 100 Market Approval Date: Not currently Approved
Seattle WA 98101

Generic Name: **Rho (D) immune globulin intravenous (human)** Trade Name: **WinRho SD**
Designated Indication: *Treatment of immune thrombocytopenic purpura.*
Sponsor: Rh Pharmaceuticals, Inc. Date Designated: 11/9/1993
Address: 104 Chancellor Matheson Road Market Approval Date: 3/24/1995
Winnipeg, Manitoba
Canada R3T 2N2 CA

Generic Name: **Ribavirin** Trade Name: **Virazole**
Designated Indication: *Treatment of hemorrhagic fever with renal syndrome.*
Sponsor: ICN Pharmaceuticals, Inc. Date Designated: 4/12/1991
Address: ICN Plaza Market Approval Date: Not currently Approved
3300 Hyland Avenue
Costa Mesa CA 92626

Generic Name: **Ricin (blocked) conjugated murine MCA (anti-B4)** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of B-cell leukemia and B-cell lymphoma.*
Sponsor: ImmunoGen, Inc. Date Designated: 11/17/1988
Address: 148 Sidney Street Market Approval Date: Not currently Approved
Cambridge MA 02139

Generic Name: **Ricin (blocked) conjugated murine mca (anti-b4)** Trade Name: **NONE ASSIGNED**
Designated Indication: *For the ex-vivo purging of leukemic cells from the bone marrow of non-T cell acute lymphocytic leukemia patients who are in complete remission.*
Sponsor: ImmunoGen, Inc. Date Designated: 1/24/1991
Address: 148 Sidney Street Market Approval Date: Not currently Approved
Cambridge MA 02139

Generic Name: **Ricin (blocked) conjugated murine MCA (anti-my9)** Trade Name: **NONE ASSIGNED**
Designated Indication: *For use in the ex-vivo treatment of autologous bone marrow and subsequent reinfusion in patients with acute myelogenous leukemia.*
Sponsor: ImmunoGen, Inc. Date Designated: 2/1/1990
Address: 148 Sidney Street Market Approval Date: Not currently Approved
Cambridge MA 02139

Generic Name: **Ricin (blocked) conjugated murine MCA (anti-my9)** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of myeloid leukemia, including AML, and blast crisis of CML.*
Sponsor: ImmunoGen, Inc. Date Designated: 8/3/1989
Address: 148 Sidney Street Market Approval Date: Not currently Approved
Cambridge MA 02139

Generic Name: **Ricin (blocked) conjugated murine MCA (n901)** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of small cell lung cancer.*
Sponsor: ImmunoGen, Inc. Date Designated: 1/25/1991
Address: 148 Sidney Street Market Approval Date: Not currently Approved
Cambridge MA 02139

Generic Name: **Ricin (blocked) conjugated murine monoclonal antibody (CD6)** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of cutaneous T-cell lymphomas, acute T-cell leukemia-lymphoma, and related mature T-cell malignancies.*
Sponsor: ImmunoGen, Inc. Date Designated: 9/6/1994
Address: 148 Sidney Street Market Approval Date: Not currently Approved
Cambridge MA 02139

Generic Name: **Rifabutin** Trade Name: **Mycobutin**
Designated Indication: *Prevention of disseminated Mycobacterium avium complex disease in patients with advanced HIV infection.*
Sponsor: Adria Laboratories, Inc. Date Designated: 12/18/1989
Address: P.O. Box 16529 Market Approval Date: 12/23/1992
Columbus OH 43216

Generic Name: **Rifabutin** Trade Name: NONE ASSIGNED
Designated Indication: *Treatment of disseminated Mycobacterium avium complex disease.*
Sponsor: Pharmacia & Upjohn Date Designated: 12/18/1989
Address: 7000 Portage Road Market Approval Date: Not currently Approved
Unit 0633-298-113
Kalamazoo MI 49001-0199

Generic Name: **Rifalazil** Trade Name: NONE ASSIGNED
Designated Indication: *Treatment of pulmonary tuberculosis.*
Sponsor: PathoGenesis Corporation Date Designated: 4/13/1999
Address: 201 Elliott Avenue West Market Approval Date: Not currently Approved
Suite 150
Seattle WA 98119

Generic Name: **Rifampin** Trade Name: Rifadin I.V.
Designated Indication: *For antituberculosis treatment where use of the oral form of the drug is not feasible.*
Sponsor: Hoechst Marion Roussel Date Designated: 12/9/1985
Address: P.O. Box 9627 Market Approval Date: 5/25/1989
Kansas City MO 64134

Generic Name: **Rifampin, isoniazid, pyrazinamide** Trade Name: Rifater
Designated Indication: *For the short-course treatment of tuberculosis.*
Sponsor: Hoechst Marion Roussel Date Designated: 9/12/1985
Address: P.O. Box 9627 Market Approval Date: 5/31/1994
Kansas City MO 64134

Generic Name: **Rifapentine** Trade Name: Priftin
Designated Indication: *Prophylactic treatment of Mycobacterium avium complex in patients with AIDS and a CD4+ count less than or equal to 75/mm3.*
Sponsor: Hoechst Marion Roussel, Inc. Date Designated: 3/12/1996
Address: P.O. Box 9627 Market Approval Date: Not currently Approved
Mail Station: H3-M2516
Kansas City MO 64134-0627

Generic Name: **Rifapentine** Trade Name: **Priftin**
Designated Indication: *Treatment of Mycobacterium avium complex in patients with AIDS.*
Sponsor: Hoechst Marion Roussel, Inc. Date Designated: 6/9/1995
Address: P.O. Box 9627 Market Approval Date: Not currently Approved
Mail Station: H3-M2516
Kansas City MO 64134-0627

Generic Name: **Rifapentine** Trade Name: **Priftin**
Designated Indication: *Treatment of pulmonary tuberculosis.*
Sponsor: Hoechst Marion Roussel Date Designated: 6/9/1995
Address: P.O. Box 9627 Market Approval Date: 6/22/1998
Mail Station: H3-M2516
Kansas City MO 64134-0627

Generic Name: **Rifaximin** Trade Name: **Normix**
Designated Indication: *Treatment of hepatic encephalopathy.*
Sponsor: Salix Pharmaceuticals, Inc. Date Designated: 2/10/1998
Address: 3600 W. Bayshore Road, Suite 205 Market Approval Date: Not currently Approved
Palo Alto CA 94303

Generic Name: **RII retinamide** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of myelodysplastic syndromes.*
Sponsor: Sparta Pharmaceuticals, Inc. Date Designated: 5/6/1993
Address: 111 Rock Road Market Approval Date: Not currently Approved
Horsham PA 19044-2310

Generic Name: **Riluzole** Trade Name: **Rilutek**
Designated Indication: *Treatment of amyotrophic lateral sclerosis.*
Sponsor: Rhone-Poulenc Rorer Pharmaceuticals, Inc. Date Designated: 3/16/1993
Address: 500 Arcola Road, P.O. Box 1200 Market Approval Date: 12/12/1995
Collegeville PA 19426

Generic Name: **Riluzole** Trade Name: **Rilutek**
Designated Indication: *Treatment of Huntington's disease.*
Sponsor: Rhone-Poulenc Rorer Pharmaceuticals, Inc. Date Designated: 10/15/1996
Address: 500 Arcola Road Market Approval Date: Not currently Approved
PO Box 5096
Collegeville PA 19426-0800

Generic Name: **Rituximab** Trade Name: **Rituxan**
Designated Indication: *Treatment of non-Hodgkin's B-cell lymphoma.*
Sponsor: IDEC Pharmaceuticals Corporation Date Designated: 6/13/1994
Address: 3030 Callan Road Market Approval Date: 11/26/1997
San Diego CA 92121

Generic Name: **rSP-C lung surfactant** Trade Name: **Venticute**
Designated Indication: *Treatment of adult respiratory distress syndrome.*
Sponsor: Byk Gulden Pharmaceuticals Date Designated: 4/3/2000
Address: Byk-Gulden StraBe 2 Market Approval Date: Not currently Approved
78467 Konstanz
Germany DE

Generic Name: **S-adenosylmethionine** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of AIDS-myelopathy.*
Sponsor: Di Rocco, Alessandro M.D. Date Designated: 4/30/1998
Address: Beth Israel Medical Center, Phillips Market Approval Date: Not currently Approved
Philips Building, Suite 2Q, 10 Union Square
New York NY 10003

Generic Name: **Sacrosidase** Trade Name: **Sucraid**
Designated Indication: *Treatment of congenital sucrase-isomaltase deficiency.*
Sponsor: Orphan Medical, Inc. Date Designated: 12/10/1993
Address: 13911 Ridgedale Drive Market Approval Date: 4/9/1998
Suite 475
Minnetonka MN 55305

Generic Name: **Sargramostim** Trade Name: **Leukine**
Designated Indication: *To reduce neutropenia and leukopenia and decrease the incidence of death due to infection in patients with acute myelogenous leukemia.*
Sponsor: **Immunex Corporation** Date Designated: **3/6/1995**
Address: **51 University Street** Market Approval Date: **9/15/1995**
Seattle WA 98101

Generic Name: **Sargramostim** Trade Name: **Leukine**
Designated Indication: *Treatment of neutropenia associated with bone marrow transplant, for the treatment of graft failure and delay of engraftment, and for the promotion of early engraftment.*
Sponsor: **Immunex Corporation** Date Designated: **5/3/1990**
Address: **51 University Street** Market Approval Date: **3/5/1991**
Seattle WA 98101

Generic Name: **Satumomab pendetide** Trade Name: **Oncoscint CR/OV**
Designated Indication: *Detection of ovarian carcinoma.*
Sponsor: **Cytogen Corporation** Date Designated: **9/25/1989**
Address: **600 College Road East** Market Approval Date: **12/29/1992**
Princeton NJ 08540

Generic Name: **SB-408075** Trade Name: **NONE ASSIGNED**
Designated Indication: *For pancreatic cancer*
Sponsor: **SmithKline Beecham Pharmaceuticals** Date Designated: **12/7/2000**
Address: **1250 S. Collegeville Road** Market Approval Date: **Not currently Approved**
Collegeville PA 19426-0989

Generic Name: **SCH 58500** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of primary ovarian cancer.*
Sponsor: **Schering Corporation** Date Designated: **4/12/1999**
Address: **2000 Galloping Hill Rd.** Market Approval Date: **Not currently Approved**
Kenilworth NJ 07033

Generic Name: **Secalciferol** Trade Name: **Osteo-D**
Designated Indication: *Treatment of familial hypophosphatemic rickets.*
Sponsor: **Teva Pharmaceuticals USA** Date Designated: **7/26/1993**
Address: **650 Cathill Rd.** Market Approval Date: **Not currently Approved**
Sellersville PA 18960

Generic Name: **Secretory leukocyte protease inhibitor** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of bronchopulmonary dysplasia.*
Sponsor: **Synergen, Inc.** Date Designated: **6/30/1992**
Address: **1885 33rd Street** Market Approval Date: **Not currently Approved**
Boulder CO 80301

Generic Name: **Selegiline HCl** Trade Name: **Eldepryl**
Designated Indication: *As an adjuvant to levodopa and carbidopa treatment of idiopathic Parkinson's disease (paralysis agitans), postencephalitic Parkinsonism, and symptomatic Parkinsonism.*
Sponsor: **Somerset Pharmaceuticals, Inc.** Date Designated: **11/7/1984**
Address: **777 South Harbor Island Boulevard** Market Approval Date: **6/5/1989**
Tampa FL 33602

Generic Name: **Sermorelin acetate** Trade Name: **Geref**
Designated Indication: *Treatment of idiopathic or organic growth hormone deficiency in children with growth failure.*
Sponsor: **Serono Laboratories, Inc.** Date Designated: **9/14/1988**
Address: **100 Longwater Circle** Market Approval Date: **9/26/1997**
Norwell MA 02061

Generic Name: **Sermorelin acetate** Trade Name: **Geref**
Designated Indication: *Adjunct to gonadotropin therapy in the induction of ovulation in women with anovulatory or oligo-ovulatory infertility who fail to ovulate in response to adequate treatment with clomiphene citrate alone and gonadotropin*
Sponsor: **Serono Laboratories, Inc.** Date Designated: **2/13/1990**
Address: **100 Longwater Circle** Market Approval Date: **Not currently Approved**
Norwell MA 02061

Generic Name: **Sermorelin acetate** Trade Name: **Geref**
Designated Indication: *Treatment of AIDS-associated catabolism/weight loss.*
Sponsor: **Serono Laboratories, Inc.** Date Designated: **12/5/1991**
Address: **100 Longwater Circle** Market Approval Date: **Not currently Approved**
Norwell MA 02061

Generic Name: **Serratia marcescens extract (polyribosomes)** Trade Name: **Imuvert**
Designated Indication: *Treatment of primary brain malignancies.*
Sponsor: **Cell Technology, Inc.** Date Designated: **9/7/1988**
Address: **1668 Valtec Lane** Market Approval Date: **Not currently Approved**
Boulder CO 80306

Generic Name: **Short chain fatty acid enema** Trade Name: **Colomed**
Designated Indication: *Treatment of chronic radiation proctitis.*
Sponsor: **Richard I. Breuer, M.D.** Date Designated: **8/19/1997**
Address: **1000 Central Street, Suite 615** Market Approval Date: **Not currently Approved**
Evanston IL 60201

Generic Name: **Short chain fatty acid solution** Trade Name: **Colomed**
Designated Indication: *Treatment of the active phase of ulcerative colitis with involvement restricted to the left side of the colon.*
Sponsor: **Richard I. Breuer** Date Designated: **5/29/1990**
Address: **1000 Central Street, Suite 615** Market Approval Date: **Not currently Approved**
Evanston IL 60201

Generic Name: **Silver sulfadiazine and cerium nitrate** Trade Name: **Flammacerium**
Designated Indication: *Prevention of mortality in severely burned patients.*
Sponsor: **Synthes (USA)** Date Designated: **11/17/1999**
Address: **1690 Russell Road** Market Approval Date: **Not currently Approved**
PO Box 1766
Paoli PA 19301

Generic Name: **Sodium 1,3-propanedisulfonate** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of secondary amyloidosis.*
Sponsor: Neurochem, Inc. Date Designated: 4/6/1999
Address: 7220 Frederick Banting, Suite 100 Market Approval Date: Not currently Approved
Saint-Laurent, Quebec
Canada H4S 2A1 CA

Generic Name: **Sodium dichloroacetate** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of homozygous familial hypercholesterolemia.*
Sponsor: Stacpoole, Peter W. M.D., Ph.D. Date Designated: 6/11/1990
Address: University of Florida Market Approval Date: Not currently Approved
P.O. Box 100277
Gainesville FL 32610

Generic Name: **Sodium dichloroacetate** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of lactic acidosis in patients with severe malaria.*
Sponsor: Stacpoole, Peter W. M.D., Ph.D. Date Designated: 11/10/1994
Address: University Of Florida Market Approval Date: Not currently Approved
P.O. Box 100277
Gainesville FL 32610

Generic Name: **Sodium dichloroacetate** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of congenital lactic acidosis.*
Sponsor: Stacpoole, Peter W. M.D., Ph.D. Date Designated: 6/11/1990
Address: University of Florida Market Approval Date: Not currently Approved
P.O. Box 100277
Gainesville FL 32610

Generic Name: **Sodium dichloroacetate** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of congenital lactic acidosis.*
Sponsor: Questcor Pharmaceuticals, Inc. Date Designated: 12/31/1997
Address: 26118 Research Road Market Approval Date: Not currently Approved
Hayward CA 94545

Generic Name: **Sodium dichloroacetate** Trade Name: **Ceresine**
Designated Indication: *Treatment of severe head injury.*
Sponsor: Questcor Pharmaceuticals, Inc. Date Designated: 6/14/1999
Address: 26118 Research Road Market Approval Date: Not currently Approved
Hayward CA 94545

Generic Name: **Sodium Monomercaptoundecahydro-ciso-dodecaborate** Trade Name: **Borocell**
Designated Indication: *For use in boron neutron capture therapy (BNCT) in the treatment of glioblastoma multiforme.*
Sponsor: Neutron Technology Corp. & Neutron R&D Date Designated: 4/15/1992
Address: 877 Main Street, Suite 402 Market Approval Date: Not currently Approved
Boise ID 83702

Generic Name: **sodium phenylbutyrate** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment for sickling disorders, which include S-S hemoglobinopathy, S-C hemoglobinopathy, and S-thalassemia hemoglobinopathy.*
Sponsor: Medicis Pharmaceutical Corp. Date Designated: 7/2/1992
Address: 8125 N. Hayden Road Market Approval Date: Not currently Approved
Scottsdale AZ 85258

Generic Name: **Sodium phenylbutyrate** Trade Name: **NONE ASSIGNED**
Designated Indication: *For use as an adjunct to surgery, radiation therapy and chemotherapy for the treatment of patients with primary or recurrent malignant glioma.*
Sponsor: Elan Pharmaceutical Research Corporation Date Designated: 4/24/1998
Address: 1300 Gould Dr. Market Approval Date: Not currently Approved
Gainesville GA 30504

Generic Name: **sodium phenylbutyrate** Trade Name: **Buphenyl**
Designated Indication: *Treatment of urea cycle disorders: carbamylphosphate synthetase deficiency, ornithine transcarbamylase deficiency, and argininosuccinic acid synthetase deficiency.*
Sponsor: Medicis Pharmaceutical Corp. Date Designated: 11/22/1993
Address: 8125 N. Hayden Road Market Approval Date: 4/30/1996
Scottsdale AZ 85258

Generic Name: **Sodium tetradecyl sulfate** Trade Name: **Sotradecol**
Designated Indication: *Treatment of bleeding esophageal varices.*
Sponsor: **Elkins-Sinn, Inc.** Date Designated: **6/10/1986**
Address: **2 Esterbrook Lane** Market Approval Date: **Not currently Approved**
Cherry Hill NJ 08003

Generic Name: **Soluble complement receptor type 1** Trade Name: **NONE ASSIGNED**
Designated Indication: *Prevention of post-cardiopulmonary bypass syndrome in children undergoing cardiopulmonary bypass.*
Sponsor: **Avant Immunotherapeutics, Inc.** Date Designated: **3/6/2000**
Address: **119 Fourth Ave.** Market Approval Date: **Not currently Approved**
Needham MA 02494-2725

Generic Name: **Soluble recombinant human complement receptor type 1** Trade Name: **NONE ASSIGNED**
Designated Indication: *Prevention or reduction of adult respiratory distress syndrome.*
Sponsor: **T Cell Sciences, Inc.** Date Designated: **11/21/1994**
Address: **119 Fourth Avenue** Market Approval Date: **Not currently Approved**
Needham Heights MA 02194

Generic Name: **Somatostatin** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of bleeding esophageal varices.*
Sponsor: **UCB Pharmaceuticals, Inc.** Date Designated: **12/22/1994**
Address: **1950 Lake Park Drive** Market Approval Date: **Not currently Approved**
Smyrna GA 30080

Generic Name: **Somatostatin** Trade Name: **Zecnil**
Designated Indication: *Adjunct to the non-operative management of secreting cutaneous fistulas of the stomach, duodenum, small intestine (jejunum and ileum), or pancreas.*
Sponsor: **Ferring Laboratories, Inc.** Date Designated: **6/20/1988**
Address: **400 Rella Boulevard, Suite 201** Market Approval Date: **Not currently Approved**
Suffern NY 10901

Generic Name: **Somatrem for injection**

Trade Name: **Protropin**

Designated Indication: *Treatment of short stature associated with Turner's syndrome.*

Sponsor: **Genentech, Inc.**
Address: **460 Point San Bruno Boulevard**
South San Francisco CA 94080

Date Designated: **12/9/1985**
Market Approval Date: **Not currently Approved**

Generic Name: **Somatrem for injection**

Trade Name: **Protropin**

Designated Indication: *For long-term treatment of children who have growth failure due to a lack of adequate endogenous growth hormone secretion.*

Sponsor: **Genentech, Inc.**
Address: **460 Point San Bruno Boulevard**
South San Francisco CA 94080

Date Designated: **12/9/1985**
Market Approval Date: **10/17/1985**

Generic Name: **Somatropin**

Trade Name: **Genotropin**

Designated Indication: *Treatment of adults with growth hormone deficiency.*

Sponsor: **Pharmacia & Upjohn**
Address: **7000 Portage Road**
Kalamazoo MI 49001-0199

Date Designated: **9/6/1994**
Market Approval Date: **10/31/1997**

Generic Name: **Somatropin**

Trade Name: **Humatrope**

Designated Indication: *Treatment of short stature associated with Turner syndrome.*

Sponsor: **Eli Lilly and Company**
Address: **Lilly Corporate Center**
Indianapolis IN 46285

Date Designated: **5/8/1990**
Market Approval Date: **12/30/1996**

Generic Name: **Somatropin**

Trade Name: **Nutropin**

Designated Indication: *For use in the long-term treatment of children who have growth failure due to a lack of adequate endogenous growth hormone secretion.*

Sponsor: **Genentech, Inc.**
Address: **460 Point San Bruno Boulevard**
South San Francisco CA 94080

Date Designated: **3/6/1987**
Market Approval Date: **10/17/1985**

Generic Name: **Somatropin (rDNA)** Trade Name: **Saizen**
Designated Indication: *For the enhancement of nitrogen retention in hospitalized patients suffering from severe burns.*
Sponsor: **Serono Laboratories, Inc.** Date Designated: **5/3/1989**
Address: **100 Longwater Circle** Market Approval Date: **Not currently Approved**
Norwell MA 02061

Generic Name: **Somatropin (r-DNA)** Trade Name: **Serostim**
Designated Indication: *For use alone or in combination with glutamine in the treatment of short bowel syndrome.*
Sponsor: **Serono Laboratories, Inc.** Date Designated: **3/6/1995**
Address: **100 Longwater Circle** Market Approval Date: **Not currently Approved**
Norwell MA 02061

Generic Name: **Somatropin (r-DNA) for injection** Trade Name: **Serostim**
Designated Indication: *Treatment of children with AIDS-associated failure-to-thrive including AIDS-associated wasting.*
Sponsor: **Serono Laboratories, Inc.** Date Designated: **3/26/1996**
Address: **100 Longwater Circle** Market Approval Date: **Not currently Approved**
Norwell MA 02061

Generic Name: **Somatropin (rDNA origin)** Trade Name: **Saizen**
Designated Indication: *Treatment of idiopathic or organic growth hormone deficiency in children with growth failure.*
Sponsor: **Serono Laboratories, Inc.** Date Designated: **3/6/1987**
Address: **100 Longwater Circle** Market Approval Date: **Not currently Approved**
Norwell MA 02061

Generic Name: **Somatropin (rDNA origin)** Trade Name: **Nutropin Depot**
Designated Indication: *Long-term treatment of children who have growth failure due to a lack of adequate endogenous growth hormone secretion.*
Sponsor: **Genentech, Inc.** Date Designated: **10/28/1999**
Address: **1 DNA Way** Market Approval Date: **Not currently Approved**
South San Francisco CA 94080-4990

Generic Name: **Somatropin (rDNA origin) injection**

Trade Name: **Norditropin**

Designated Indication: *Treatment of growth failure in children due to inadequate growth hormone secretion.*

Sponsor: **Novo Nordisk Pharmaceuticals**
Address: **100 Overlook Center
Suite 200
Princeton NJ 08540**

Date Designated: **7/10/1987**
Market Approval Date: **Not currently Approved**

Generic Name: **somatropin [rDNA]**

Trade Name: **Genotropin**

Designated Indication: *Treatment of growth failure in children who were born small for gestational age.*

Sponsor: **Pharmacia and Upjohn Company**
Address: **7000 Portage Road
Kalamazoo MI 49001**

Date Designated: **12/27/2000**
Market Approval Date: **7/25/2001**

Generic Name: **Somatropin [rDNA]**

Trade Name: **Genotropin**

Designated Indication: *Treatment of short stature in patients with Prader-Willi syndrome.*

Sponsor: **Pharmacia & Upjohn**
Address: **7000 Portage Rd.
0633-298-113
Kalamazoo MI 49001-0199**

Date Designated: **7/6/1999**
Market Approval Date: **6/20/2000**

Generic Name: **Somatropin for injection**

Trade Name: **Nutropin**

Designated Indication: *Treatment of short stature associated with Turner's syndrome.*

Sponsor: **Genentech, Inc.**
Address: **460 Point San Bruno Boulevard
South San Francisco CA 94080**

Date Designated: **3/23/1989**
Market Approval Date: **12/30/1996**

Generic Name: **Somatropin for injection**

Trade Name: **Nutropin**

Designated Indication: *Treatment of growth retardation associated with chronic renal failure.*

Sponsor: **Genentech, Inc.**
Address: **460 Point San Bruno Boulevard
South San Francisco CA 94080**

Date Designated: **8/4/1989**
Market Approval Date: **11/17/1993**

Generic Name: **Somatropin for injection** Trade Name: **Humatrope**
Designated Indication: *For the long-term treatment of children who have growth failure due to inadequate secretion of normal endogenous growth hormone.*
Sponsor: **Eli Lilly and Company** Date Designated: **6/12/1986**
Address: **Lilly Corporate Center** Market Approval Date: **3/8/1987**
Indianapolis IN 46285

Generic Name: **Somatropin for injection** Trade Name: **Serostim**
Designated Indication: *Treatment of AIDS-associated catabolism/weight loss.*
Sponsor: **Serono Laboratories, Inc.** Date Designated: **11/15/1991**
Address: **100 Longwater Circle** Market Approval Date: **8/23/1996**
Norwell MA 02061

Generic Name: **Somatropin for injection** Trade Name: **Nutropin**
Designated Indication: *As replacement therapy for growth hormone deficiency in adults after epiphyseal closure.*
Sponsor: **Genentech, Inc.** Date Designated: **11/18/1996**
Address: **460 Point San Bruno Boulevard** Market Approval Date: **12/15/1997**
South San Francisco CA 94080

Generic Name: **Sotalol HCl** Trade Name: **Betapace**
Designated Indication: *Treatment of life-threatening ventricular tachyarrhythmias.*
Sponsor: **Berlex Laboratories, Inc.** Date Designated: **9/23/1988**
Address: **300 Fairfield Road** Market Approval Date: **10/30/1992**
Wayne NJ 07470

Generic Name: **squalamine lactate** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of ovarian cancer refractory or resistant to standard chemotherapy*
Sponsor: **Genaera Corporation** Date Designated: **5/11/2001**
Address: **5110 Campus Drive** Market Approval Date: **Not currently Approved**
Plymouth Meeting PA 19462

Generic Name: **Sterile talc** Trade Name: **Steritalc**
Designated Indication: *Treatment of malignant pleural effusion.*
Sponsor: Novatech SA Date Designated: 12/8/1997
Address: Avenue du Vent des Dames - Z.I. les Paluds Market Approval Date: Not currently Approved
13685 Aubagne
France

Generic Name: **Sterile talc** Trade Name: **Steritalc**
Designated Indication: *Treatment of pneumothorax.*
Sponsor: Novatech SA Date Designated: 12/8/1997
Address: Avenue du Vent des Dames - Z.I. les Paluds Market Approval Date: Not currently Approved
13685 Aubagne
France

Generic Name: **Sterile talc powder** Trade Name: **Sclerosol Intrapleural Aerosol**
Designated Indication: *Treatment of malignant pleural effusion.*
Sponsor: Bryan Corporation Date Designated: 9/18/1995
Address: 4 Plympton Street Market Approval Date: 12/24/1997
Woburn MA 01801

Generic Name: **SU101** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of ovarian cancer.*
Sponsor: Sugan, Inc. Date Designated: 3/12/1996
Address: 230 East Grand Ave. Market Approval Date: Not currently Approved
South San Francisco CA 94080-4811

Generic Name: **SU101** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of malignant glioma.*
Sponsor: Sugan, Inc. Date Designated: 5/25/1995
Address: 230 East Grand Ave. Market Approval Date: Not currently Approved
South San Francisco CA 94080-4811

Generic Name: **Succimer** Trade Name: **Chemet**
Designated Indication: *Prevention of cystine kidney stone formation in patients with homozygous cystinuria who are prone to stone development.*
Sponsor: **Sanofi Winthrop, Inc.** Date Designated: **11/5/1990**
Address: **90 Park Avenue** Market Approval Date: **Not currently Approved**
New York NY 10016-1389

Generic Name: **Succimer** Trade Name: **Chemet capsules**
Designated Indication: *Treatment of lead poisoning in children.*
Sponsor: **Bock Pharmacal Company** Date Designated: **5/9/1984**
Address: **P.O. Box 419056** Market Approval Date: **12/22/1988**
Saint Louis MO 63141-9056

Generic Name: **Succimer** Trade Name: **Chemet**
Designated Indication: *Treatment of mercury intoxication.*
Sponsor: **Sanofi Winthrop, Inc.** Date Designated: **3/22/1991**
Address: **90 Park Avenue** Market Approval Date: **Not currently Approved**
New York NY 10016-1389

Generic Name: **Sucralfate suspension** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of oral complications of chemotherapy in bone marrow transplant patients.*
Sponsor: **Darby Pharmaceuticals, Inc.** Date Designated: **3/12/1990**
Address: **100 Banks Avenue** Market Approval Date: **Not currently Approved**
Rockville Centre NY 11570

Generic Name: **Sucralfate suspension** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of oral ulcerations and dysphagia in patients with epidermolysis bullosa.*
Sponsor: **Darby Pharmaceuticals, Inc.** Date Designated: **3/4/1991**
Address: **100 Banks Avenue** Market Approval Date: **Not currently Approved**
Rockville Centre NY 11570

Generic Name: **Sulfadiazine** Trade Name: **NONE ASSIGNED**

Designated Indication: *For use in combination with pyrimethamine for the treatment of Toxoplasma gondii encephalitis in patients with and without AIDS.*

Sponsor: **Eon Labs Manufacturing, Inc.** Date Designated: **3/14/1994**
Address: **227-15 North Conduit Avenue** Market Approval Date: **7/29/1994**
Laurelton NY 11413

Generic Name: **Sulfapyridine** Trade Name: **NONE ASSIGNED**

Designated Indication: *Treatment of dermatitis herpetiformis.*

Sponsor: **Jacobus Pharmaceutical Company** Date Designated: **9/10/1990**
Address: **37 Cleveland Lane** Market Approval Date: **Not currently Approved**
P.O. Box 5290
Princeton NJ 08540

Generic Name: **Superoxide dismutase (human)** Trade Name: **NONE ASSIGNED**

Designated Indication: *For protection of donor organ tissue from damage or injury mediated by oxygen-derived free radicals that are generated during the necessary periods of ischemia (hypoxia, anoxia), and especially reperfusion, associated with the operative procedure.*

Sponsor: **Pharmacia-Chiron Partnership** Date Designated: **3/6/1985**
Address: **4560 Horton Street** Market Approval Date: **Not currently Approved**
Emeryville CA 94608

Generic Name: **Suramin** Trade Name: **Metarex**

Designated Indication: *Treatment of hormone-refractory prostate cancer.*

Sponsor: **Warner-Lambert Company** Date Designated: **5/6/1997**
Address: **Parke-Davis Pharmaceutical Research** Market Approval Date: **Not currently Approved**
2800 Plymouth Road
Ann Arbor MI 48105-2430

Generic Name: **Surface active extract of saline lavage of bovine lungs** Trade Name: **Infasurf**

Designated Indication: *Treatment and prevention of respiratory failure due to pulmonary surfactant deficiency in preterm infants.*

Sponsor: **ONY, Inc.** Date Designated: **6/7/1985**
Address: **1576 Sweet Home Road** Market Approval Date: **Not currently Approved**
Amherst NY 14228

Generic Name: **Synsorb Pk** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of verocytotoxigenic E. coli infections.*
Sponsor: Synsorb Biotech Inc. Date Designated: 7/17/1995
Address: 201, 1204 Kensington Road, N.W. Market Approval Date: Not currently Approved
Calgary, Alberta
Canada T2N 3P5 CA

Generic Name: **Synthetic Human Parathyroid Hormone 1-34** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of hypoparathyroidism*
Sponsor: Orphan Pharmaceuticals, U.S., Inc. Date Designated: 1/26/2001
Address: 1101 Kermit Drive, Market Approval Date: Not currently Approved
Suite 608
Nashville TN 37217

Generic Name: **Synthetic human secretin** Trade Name: **NONE ASSIGNED**
Designated Indication: *For use in the evaluation of exocrine pancreas function.*
Sponsor: ChiRhoClin, Inc. Date Designated: 6/16/1999
Address: 1550 Gallaudet Ave. Market Approval Date: Not currently Approved
Silver Spring MD 20905-4176

Generic Name: **Synthetic human secretin** Trade Name: **NONE ASSIGNED**
Designated Indication: *For use in obtaining desquamated pancreatic cells for cytopathologic examination in pancreatic carcinoma.*
Sponsor: ChiRhoClin, Inc. Date Designated: 6/16/1999
Address: 15500 Gallaudet Ave. Market Approval Date: Not currently Approved
Silver Spring MD 20905-4176

Generic Name: **Synthetic human secretin** Trade Name: **NONE ASSIGNED**
Designated Indication: *For use in the diagnosis of gastrinoma associated with Zollinger-Ellison syndrome.*
Sponsor: ChiRhoClin, Inc. Date Designated: 6/16/1999
Address: 15500 Gallaudet Ave. Market Approval Date: Not currently Approved
Silver Spring MD 20905-4176

Generic Name: **Synthetic human secretin** Trade Name: **NONE ASSIGNED**
Designated Indication: *For use in conjunction with diagnostic procedures for pancreatic disorders to increase pancreatic fluid secretion.*
Sponsor: **ChiRhoClin, Inc.** Date Designated: **3/7/2000**
Address: **15500 Gallaudet Ave.** Market Approval Date: **Not currently Approved**
Silver Spring MD 20905-4176

Generic Name: **Synthetic porcine secretin** Trade Name: **NONE ASSIGNED**
Designated Indication: *For use in the evaluation of exocrine pancreas function.*
Sponsor: **ChiRhoClin, Inc.** Date Designated: **6/18/1999**
Address: **15500 Gallaudet Ave.** Market Approval Date: **Not currently Approved**
Silver Spring MD 20905-4176

Generic Name: **Synthetic porcine secretin** Trade Name: **NONE ASSIGNED**
Designated Indication: *For use in obtaining desquamated pancreatic cells for cytopathologic examination in pancreatic carcinoma.*
Sponsor: **ChiRhoClin, Inc.** Date Designated: **6/18/1999**
Address: **15500 Gallaudet Ave.** Market Approval Date: **Not currently Approved**
Silver Spring MD 20905-4176

Generic Name: **Synthetic porcine secretin** Trade Name: **NONE ASSIGNED**
Designated Indication: *For use in conjunction with diagnostic procedures for pancreatic disorders to increase pancreatic fluid secretion.*
Sponsor: **ChiRhoClin, Inc.** Date Designated: **3/7/2000**
Address: **15500 Gallaudet Ave.** Market Approval Date: **Not currently Approved**
Silver Spring MD 20905-4176

Generic Name: **Synthetic porcine secretin** Trade Name: **NONE ASSIGNED**
Designated Indication: *For use in the diagnosis of gastrinoma associated with Zollinger-Ellison syndrome.*
Sponsor: **ChiRhoClin, Inc.** Date Designated: **6/18/1999**
Address: **15500 Gallaudet Ave.** Market Approval Date: **Not currently Approved**
Silver Spring MD 20905-4176

Generic Name: **T4 endonuclease V, liposome encapsulated** Trade Name: **NONE ASSIGNED**
Designated Indication: *To prevent cutaneous neoplasms and other skin abnormalities in xeroderma pigmentosum.*
Sponsor: **AGI Dermatics** Date Designated: **6/27/1989**
Address: **205 Buffalo Avenue** Market Approval Date: **Not currently Approved**
Freeport NY 11520

Generic Name: **Tacrolimus** Trade Name: **Prograf**
Designated Indication: *Prophylaxis of graft-versus-host-disease.*
Sponsor: **Fujisawa USA, Inc.** Date Designated: **4/6/1998**
Address: **3 Parkway North Center** Market Approval Date: **Not currently Approved**
Deerfield IL 60015

Generic Name: **Technetium Tc 99m pterotetramide** Trade Name: **NONE ASSIGNED**
Designated Indication: *For the identification of ovarian carcinomas.*
Sponsor: **Endocyte, Inc.** Date Designated: **2/16/2000**
Address: **1205 Kent Ave.** Market Approval Date: **Not currently Approved**
Lafayette IN 47906

Generic Name: **Technetium Tc99m murine monoclonal antibody (IgG2a) to B cell** Trade Name: **LymphoScan**
Designated Indication: *Diagnostic imaging in the evaluation of the extent of disease in patients with histologically confirmed diagnosis of non-Hodgkin's B-cell lymphoma, acute B-cell lymphoblastic leukemia (in children and adults), and chronic B-cell lymphocytic leukemia.*
Sponsor: **Immunomedics, Inc.** Date Designated: **4/7/1992**
Address: **300 American Road** Market Approval Date: **Not currently Approved**
Morris Plains NJ 07950

Generic Name: **Technetium Tc99m murine monoclonal antibody to hCG** Trade Name: **Immuraid, hCG-Tc-99m**
Designated Indication: *Detection of hCG producing tumors such as germ cell and trophoblastic cell tumors.*
Sponsor: **Immunomedics, Inc.** Date Designated: **8/7/1989**
Address: **300 American Road** Market Approval Date: **Not currently Approved**
Morris Plains NJ 07950

Generic Name: **Technetium Tc99m murine monoclonal antibody to human AFP** Trade Name: **AFP-Scan**
Designated Indication: *Detection of alpha-fetoprotein producing germ cell tumors.*
Sponsor: Immunomedics, Inc. Date Designated: 8/1/1989
Address: 300 American Road Market Approval Date: Not currently Approved
Morris Plains NJ 07950

Generic Name: **Technetium Tc99m murine monoclonal antibody to human alpha-fetoprotein** Trade Name: **Immuraid, AFP-Scan**
Designated Indication: *Detection of hepatocellular carcinoma and hepatoblastoma.*
Sponsor: Immunomedics, Inc. Date Designated: 8/1/1989
Address: 300 American Road Market Approval Date: Not currently Approved
Morris Plains NJ 07950

Generic Name: **Technetium Tc99m rh-Annexin V** Trade Name: **Apomate**
Designated Indication: *Diagnosis or assessment of rejection status in heart, heart-lung, single lung, or bilateral lung transplants.*
Sponsor: Theseus Imaging Corporation Date Designated: 11/3/2000
Address: 124 Mount Auburn Street Market Approval Date: Not currently Approved
Suite 200 North
Cambridge MA 02138

Generic Name: **Temoporfin** Trade Name: **Foscan**
Designated Indication: *Palliative treatment of recurrent, refractory or second primary squamous cell carcinomas of the head and neck in patients considered to be incurable with surgery or radiotherapy.*
Sponsor: Scotia Pharmaceuticals Ltd. Date Designated: 10/28/1999
Address: Scotia House, Castle Business Park Market Approval Date: Not currently Approved
Stirling
Scotland FK9 4TZ GB

Generic Name: **Temozolomide** Trade Name: **Temodal**
Designated Indication: *Treatment of advanced metastatic melanoma.*
Sponsor: Schering-Plough Research Institute Date Designated: 10/14/1998
Address: 2000 Galloping Hill Rd. Market Approval Date: Not currently Approved
Kenilworth NJ 07033

Generic Name: **Temozolomide**

Trade Name: **Temodar**

Designated Indication: *Treatment of recurrent malignant glioma.*

Sponsor: **Schering-Plough Research Institute**
Address: **2000 Galloping Hill Rd.
Kenilworth NJ 07033**

Date Designated: **10/5/1998**
Market Approval Date: **8/11/1999**

Generic Name: **Teniposide**

Trade Name: **Vumon for injection**

Designated Indication: *Treatment of refractory childhood acute lymphocytic leukemia.*

Sponsor: **Bristol-Myers Squibb Pharmaceutical**
Address: **5 Research Parkway
P.O. Box 5100
Wallingford CT 06492**

Date Designated: **11/1/1984**
Market Approval Date: **7/14/1992**

Generic Name: **Teriparatide**

Trade Name: **Parathar**

Designated Indication: *Treatment of idiopathic osteoporosis.*

Sponsor: **Henri Beaufour Institute USA, Inc.**
Address: **27 Maple St.
Milford MA 01757**

Date Designated: **10/28/1999**
Market Approval Date: **Not currently Approved**

Generic Name: **Teriparatide**

Trade Name: **Parathar**

Designated Indication: *Diagnostic agent to assist in establishing the diagnosis in patients presenting with clinical and laboratory evidence of hypocalcemia due to either hypoparathyroidism or pseudohypoparathyroidism.*

Sponsor: **Rhone-Poulenc Rorer Pharmaceuticals, Inc.**
Address: **500 Arcola Road
Collegeville PA 19426**

Date Designated: **1/9/1987**
Market Approval Date: **12/23/1987**

Generic Name: **Terlipressin**

Trade Name: **Glypressin**

Designated Indication: *Treatment of bleeding esophageal varices.*

Sponsor: **Ferring Laboratories, Inc.**
Address: **400 Rella Boulevard, Suite 201
Suffern NY 10901**

Date Designated: **3/6/1986**
Market Approval Date: **Not currently Approved**

Generic **Testosterone** Trade TheraDerm Testosterone Transdermal System
Name: Name:
Designated *For use as physiologic testosterone replacement in androgen deficient HIV+ patients with an associated weight*
Indication: *loss.*
Sponsor: Watson Laboratories Date Designated: 9/22/1997
Address: Research Park Market Approval Date: Not currently Approved
417 Wakara Way
Salt Lake City UT 84108

Generic **Testosterone** Trade Androgel
Name: Name:
Designated *Treatment of weight loss in AIDS patients with HIV-associated wasting.*
Indication:
Sponsor: Unimed Pharmaceuticals, Inc. Date Designated: 2/5/1996
Address: Four Parkway North Market Approval Date: Not currently Approved
Deerfield IL 60015-2544

Generic **Testosterone propionate ointment 2%** Trade NONE ASSIGNED
Name: Name:
Designated *Treatment of vulvar dystrophies.*
Indication:
Sponsor: Star Pharmaceuticals, Inc. Date Designated: 7/31/1991
Address: 1990 N.W. 44th Street Market Approval Date: Not currently Approved
Pompano Beach FL 33064

Generic **Tetrabenazine** Trade NONE ASSIGNED
Name: Name:
Designated *Treatment of Huntington's disease.*
Indication:
Sponsor: Lifehealth Limited Date Designated: 12/11/1997
Address: 23 Winkfield Road Market Approval Date: Not currently Approved
Windor, Berkshire
SL4 4BA UK

Generic **Tetrabenazine** Trade NONE ASSIGNED
Name: Name:
Designated *Treatment of moderate/severe tardive dyskinesia.*
Indication:
Sponsor: Lifehealth Limited Date Designated: 5/12/1998
Address: 23 Winkfield Road Market Approval Date: Not currently Approved
Windsor, Berkshire
SL4 4BA UK

Generic Name: **Tetraiodothyroacetic acid** Trade Name: **NONE ASSIGNED**
Designated Indication: *Suppression of thyroid stimulating hormone in patients with well-differentiated cancer of the thyroid gland.*
Sponsor: Danforth, Jr., MD, Elliot Date Designated: 5/1/2000
Address: University of Vermont Market Approval Date: Not currently Approved
84 Beartown Rd.
Underhill VT 05489

Generic Name: **Thalidomide** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment and prevention of recurrent aphthous ulcers in severely, terminally immunocompromised patients.*
Sponsor: Andrulis Research Corporation Date Designated: 5/15/1995
Address: 11800 Baltimore Avenue, Suite 113 Market Approval Date: Not currently Approved
Beltsville MD 20705

Generic Name: **Thalidomide** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of severe recurrent aphthous stomatitis in severely, terminally immunocompromised patients.*
Sponsor: Celgene Corporation Date Designated: 5/1/1995
Address: P.O. Box 4914 Market Approval Date: Not currently Approved
7 Powder Horn Drive
Warren NJ 07059

Generic Name: **Thalidomide** Trade Name: **Thalomid**
Designated Indication: *Treatment of Crohn's disease.*
Sponsor: Celgene Corporation Date Designated: 4/6/1999
Address: 7 Powder Horn Dr. Market Approval Date: Not currently Approved
Warren NJ 07059

Generic Name: **Thalidomide** Trade Name: **Thalomid**
Designated Indication: *Treatment of multiple myeloma.*
Sponsor: Celgene Corporation Date Designated: 10/14/1998
Address: 7 Powder Horn Dr. Market Approval Date: Not currently Approved
Warren NJ 07059

Generic **Thalidomide**
Name:

Trade **Thalomid**
Name:

Designated *Treatment of erythema nodosum leprosum.*
Indication:

Sponsor: Celgene Corporation
Address: P.O. Box 4914
7 Powder Horn Drive
Warren NJ 07059

Date Designated: 7/26/1995
Market Approval Date: 7/16/1998

Generic **Thalidomide**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of Kaposi's sarcoma.*
Indication:

Sponsor: Celgene Corporation
Address: 7 Powder Horn Dr.
Warren NJ 07059

Date Designated: 7/29/1998
Market Approval Date: Not currently Approved

Generic **Thalidomide**
Name:

Trade **Synovir**
Name:

Designated *Treatment of HIV-associated wasting syndrome.*
Indication:

Sponsor: Celgene Corporation
Address: P.O. Box 4914
7 Powder Horn Drive
Warren NJ 07059

Date Designated: 3/11/1996
Market Approval Date: Not currently Approved

Generic **Thalidomide**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment and maintenance of reactional lepromatous leprosy.*
Indication:

Sponsor: Pediatric Pharmaceuticals, Inc.
Address: 718 Bradford Avenue
Westfield NJ 07090

Date Designated: 11/15/1988
Market Approval Date: Not currently Approved

Generic **Thalidomide**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of graft versus host disease.*
Indication:

Sponsor: Andrulis Research Corporation
Address: 11800 Baltimore Avenue, Suite 113
Beltsville MD 20705

Date Designated: 3/5/1990
Market Approval Date: Not currently Approved

Generic Name: **Thalidomide** Trade Name: **NONE ASSIGNED**
Designated Indication: *Prevention of graft versus host disease.*
Sponsor: **Andrulis Research Corporation** Date Designated: **3/5/1990**
Address: **11800 Baltimore Avenue, Suite 113** Market Approval Date: **Not currently Approved**
Beltsville MD 20705

Generic Name: **Thalidomide** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of graft versus host disease in patients receiving bone marrow transplantation.*
Sponsor: **Pediatric Pharmaceuticals, Inc.** Date Designated: **9/19/1988**
Address: **718 Bradford Avenue** Market Approval Date: **Not currently Approved**
Westfield NJ 07090

Generic Name: **Thalidomide** Trade Name: **NONE ASSIGNED**
Designated Indication: *Prevention of graft versus host disease in patients receiving bone marrow transplantation.*
Sponsor: **Pediatric Pharmaceuticals, Inc.** Date Designated: **9/19/1988**
Address: **718 Bradford Avenue** Market Approval Date: **Not currently Approved**
Westfield NJ 07090

Generic Name: **Thalidomide** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of primary brain malignancies.*
Sponsor: **Celgene Corporation** Date Designated: **2/27/1998**
Address: **7 Powder Horn Dr.** Market Approval Date: **Not currently Approved**
Warren NJ 07059

Generic Name: **Thalidomide** Trade Name: **NONE ASSIGNED**
Designated Indication: *Treatment of the clinical manifestations of mycobacterial infection caused by Mycobacterium tuberculosis and non-tuberculous mycobacteria.*
Sponsor: **Celgene Corporation** Date Designated: **1/12/1993**
Address: **P.O. Box 4914** Market Approval Date: **Not currently Approved**
7 Powder Horn Drive
Warren NJ 07059

Generic Name: **Thymalfasin**

Trade Name: **Zadaxin**

Designated Indication: *Treatment of chronic active hepatitis B.*

Sponsor: **SciClone Pharmaceuticals, Inc.**
Address: **901 Mariner's Island Blvd.
San Mateo CA 94404-1593**

Date Designated: **5/3/1991**
Market Approval Date: **Not currently Approved**

Generic Name: **Thymalfasin**

Trade Name: **Zadaxin**

Designated Indication: *Treatment of hepatocellular carcinoma.*

Sponsor: **SciClone Pharmaceuticals, Inc.**
Address: **901 Mariner's Blvd., Suite 205
San Mateo CA 94404**

Date Designated: **3/6/2000**
Market Approval Date: **Not currently Approved**

Generic Name: **Thymalfasin**

Trade Name: **Zadaxin**

Designated Indication: *Treatment of DiGeorge anomaly with immune defects.*

Sponsor: **SciClone Pharmaceuticals, Inc.**
Address: **901 Mariner's Island Blvd.
San Mateo CA 94404-1593**

Date Designated: **1/8/1998**
Market Approval Date: **Not currently Approved**

Generic Name: **Thyrotropin alfa**

Trade Name: **Thyrogen**

Designated Indication: *Treatment of well-differentiated papillary, follicular or combined papillary/follicular carcinomas of the thyroid*

Sponsor: **Genzyme Corporation**
Address: **One Kendall Square
Cambridge MA 02139-1562**

Date Designated: **8/3/2001**
Market Approval Date: **Not currently Approved**

Generic Name: **Thyrotropin alpha**

Trade Name: **Thyrogen**

Designated Indication: *As an adjunct in the diagnosis of thyroid cancer.*

Sponsor: **Genzyme Corporation**
Address: **One Kendall Square
Cambridge MA 02139**

Date Designated: **2/24/1992**
Market Approval Date: **11/30/1998**

Generic Name: **Tiazofurin**
(2-Beta-D-ribofuranosyl-4-thiazolecarboxamide)

Trade Name: NONE ASSIGNED

Designated Indication: *Chronic myelogenous leukemia (CML)*

Sponsor: ICN Pharmaceuticals, Inc. (ICN)
Address: 3300 Hyland Avenue
Costa Mesa CA 92626

Date Designated: 12/27/2000
Market Approval Date: Not currently Approved

Generic Name: **Tiopronin**

Trade Name: Thiola

Designated Indication: *Prevention of cystine nephrolithiasis in patients with homozygous cystinuria.*

Sponsor: Pak, Charles Y.C. M.D.
Address: The University of Texas Health Science Center
5323 Harry Hines Boulevard
Dallas TX 75235

Date Designated: 1/17/1986
Market Approval Date: 8/11/1988

Generic Name: **Tiratricol**

Trade Name: Triacana

Designated Indication: *For use in combination with levo-thyroxine to suppress thyroid stimulating hormone in patients with well-differentiated thyroid cancer who are intolerant to adequate doses of levo-thyroxine alone.*

Sponsor: Laphal Laboratoires
Address: 48 Bis, Rue des Belles-Feuilles
75116 Paris
France FR

Date Designated: 8/13/1991
Market Approval Date: Not currently Approved

Generic Name: **Tizanidine HCl**

Trade Name: Zanaflex

Designated Indication: *Treatment of spasticity associated with multiple sclerosis and spinal cord injury.*

Sponsor: Athena Neurosciences, Inc.
Address: 800 Gateway Boulevard
South San Francisco CA 94080

Date Designated: 1/31/1994
Market Approval Date: Not currently Approved

Generic Name: **Tobramycin**

Trade Name: Tobl

Designated Indication: *Treatment of bronchiectasis patients infected with Pseudomonas aeruginosa.*

Sponsor: Chiron Corporation
Address: 201 Elliott Avenue West
Suite 150
Seattle WA 98119

Date Designated: 6/18/1999
Market Approval Date: Not currently Approved

Generic **Tobramycin for inhalation**
Name:

Trade **TOBI**
Name:

Designated *Treatment of bronchopulmonary infections of Pseudomonas aeruginosa in cystic fibrosis patients.*
Indication:

Sponsor: Pathogenesis Corporation
Address: 201 Elliott Avenue West, Suite 150
Seattle WA 98119

Date Designated: 10/13/1994
Market Approval Date: 12/22/1997

Generic **Topiramate**
Name:

Trade **Topamax**
Name:

Designated *Treatment of Lennox-Gastaut syndrome.*
Indication:

Sponsor: R. W. Johnson Pharmaceutical Research
Address: Route 202, P.O. Box 300
Raritan NJ 08869-0602

Date Designated: 11/25/1992
Market Approval Date: 8/28/2001

Generic **Toremifene**
Name:

Trade **Fareston**
Name:

Designated *Hormonal therapy of metastatic carcinoma of the breast.*
Indication:

Sponsor: Orion Corporation
Address: P.O. Box 65
02101 ESPOO
Finland

Date Designated: 9/19/1991
Market Approval Date: 5/29/1997

Generic **Toremifene**
Name:

Trade **NONE ASSIGNED**
Name:

Designated *Treatment of desmoid tumors.*
Indication:

Sponsor: Orion Corporation
Address: P.O. Box 65
02101 Espoo
Finland

Date Designated: 8/17/1993
Market Approval Date: Not currently Approved

Generic **Tositumomab and iodine I 131 tositumomab**
Name:

Trade **Bexxar**
Name:

Designated *Treatment of non-Hodgkin's B-cell lymphoma.*
Indication:

Sponsor: Coulter Pharmaceutical, Inc.
Address: 550 California Avenue
Suite 200
Palo Alto CA 94306

Date Designated: 5/16/1994
Market Approval Date: Not currently Approved